(PR as low as 0.83 in the FULL_BENEFIT_DISABLED segment) and for beneficiaries with many conditions (PR as low as 0.90 for the NONDUAL_DISABLED segment who have 12 or more conditions). It may be counterintuitive that V22 underpredicted costs for a population that appeared to be quite healthy, those with no conditions indicated in the model. This underprediction occurred because many of these beneficiaries do have medical conditions, but the conditions are not included in V22; the model does not adjust payments for those medical conditions. This underprediction occurs in the other versions we evaluated for the same reason.[3]

We also included in Table 4-1 (p. 108) PRs for beneficiaries with conditions not included in V22 but which CMS added to V23 in 2019 (moderate to severe substance abuse, mild substance abuse, reactive and unspecified psychosis, personality disorder, and Stage 3 chronic kidney disease). In general, PRs for these conditions are less than 1.0, indicating costs are underpredicted. This result is not surprising. If a risk adjustment model does not account for a medical condition, there is no payment adjustment if a beneficiary has that condition.

Finally, when we stratified beneficiaries in each population segment by their Medicare spending in the base year, we found that for each population segment model, V22 systematically overpredicted the cost of beneficiaries with low Medicare spending in the base year and underpredicted the cost of beneficiaries with high Medicare spending in the base year. For example, under V22 for the FULL_BENEFIT_DISABLED segment, the PR for those with base-year spending in the lowest 20 percent was 1.47, indicating an average overpayment of 47 percent. At the same time, the PR for those with base-year spending at the 99th percentile or higher was 0.63, indicating an average underpayment of 37 percent. Large, systematic underpayments and overpayments are an incentive for MA plans to encourage the enrollment of beneficiaries for whom plans are systematically overpaid and discourage enrollment of beneficiaries for whom plans are systematically underpaid.

In summary, we found that V22 predicts costs well for each of the seven population segments and for groups of beneficiaries within those population segments who have conditions included in V22 (AMI, cancer, and so on). However, CMS–HCC model V22 does not predict as accurately when we group beneficiaries by variables not in the model.

Adding variables for substance abuse disorders, mental health disorders, and chronic kidney disease to the models improves cost prediction for those conditions but could increase coding opportunities

In 2019, CMS implemented a new version of the CMS–HCC model—V23—after making several changes to the HCCs in V22, which included new HCCs for mild substance abuse, reactive and unspecified psychosis, personality disorder, and Stage 3 chronic kidney disease. In addition, CMS expanded the HCC for moderate to severe substance abuse by adding more diagnoses that map to that HCC. For V23, CMS continued to provide separate estimates for the seven population segments used in V22.

We find that—relative to V22—V23 improved prediction for some beneficiary groups and had similar predictions for other beneficiary groups. We expected that V23 would produce better PRs than V22 for the beneficiaries with diagnoses that map into the five HCCs that CMS added to or expanded for V23. For example, the predictive ratios under V22 for the six community population segments ranged from 0.80 to 0.89 for reactive or unspecified psychosis (Table 4-1, p. 108). Under V23, the PRs for reactive or unspecified psychosis improved in all of the population segments, ranging from 0.97 to 1.00 (Table 4-2, p. 109). Despite the general improvement in PRs for these five HCCs under V23, the PRs in Table 4-2 are still well below 1.00 in some instances, such as a PR of 0.84 for personality disorder in the PARTIAL_BENEFIT_AGED population. In our view, these low PRs are not a sign of poor performance by V23. Instead, we attribute the few low PRs among these five HCCs to small numbers of beneficiaries who have these conditions. For example, we used a sample of 13.6 million to evaluate PRs, but only 271 beneficiaries who were in the PARTIAL_BENEFIT_AGED segment had the HCC for personality disorder. Under samples that small, a few beneficiaries with very high costs or very low costs can substantially affect the level of the PR. For example, the two highest cost beneficiaries in the sample we used to determine PRs had costs of $427,000 and $330,000, while the highest cost beneficiary in the sample we used to estimate V23 had costs of $253,000.

TABLE 4-1

Predictive ratios for CMS–HCC model V22

	Full Medicaid		Partial Medicaid		No Medicaid		
Beneficiary category	**Disabled**	**Aged**	**Disabled**	**Aged**	**Disabled**	**Aged**	**LTI**
R^2	0.123	0.116	0.081	0.105	0.080	0.122	0.096
Conditions in model V22							
AMI	1.02	0.99	0.99	1.00	0.98	1.02	1.02
Cancer	1.01	1.00	1.01	0.99	0.99	1.00	1.01
CHF	1.02	1.00	1.01	1.00	0.99	1.00	1.01
COPD	1.01	1.00	1.00	1.00	1.00	1.00	1.00
Diabetes	1.01	1.00	1.00	1.00	1.01	1.00	1.00
Mental illness	1.00	1.00	1.00	0.98	1.00	1.00	1.01
Schizophrenia	1.00	0.97	0.99	0.99	1.00	0.98	1.01
All stroke	0.99	0.98	1.02	0.98	0.98	0.99	1.01
Ischemic or unspecified stroke	0.99	0.98	1.02	0.98	0.98	1.00	1.00
Number of conditions (added in model V24.1)							
No conditions	0.83	0.90	0.89	0.92	0.86	0.96	0.82
1 condition	0.98	1.02	1.01	1.01	1.00	1.01	0.98
2 conditions	1.02	1.02	1.02	1.02	1.04	1.02	1.02
3 conditions	1.04	1.02	1.02	1.01	1.05	1.01	1.02
4 conditions	1.03	1.02	1.03	1.02	1.04	1.01	1.03
5 or more conditions	1.01	1.00	1.00	1.00	1.00	1.00	1.00
8 or more conditions	0.99	0.97	0.98	0.96	0.95	0.97	0.99
10 or more conditions	0.97	0.95	0.95	0.93	0.93	0.96	0.99
12 or more conditions	0.95	0.94	0.94	0.92	0.90	0.94	0.98
Percentile of base-year cost							
0 to 20 percentile	1.47	1.04	1.40	1.12	1.72	1.29	0.84
20 to 40 percentile	1.54	1.37	1.53	1.34	1.67	1.33	1.51
40 to 60 percentile	1.27	1.24	1.24	1.17	1.23	1.13	1.32
60 to 80 percentile	1.06	1.05	1.04	1.01	0.97	0.96	1.04
80 to 95 percentile	0.92	0.91	0.92	0.88	0.83	0.88	0.96
95 to 99 percentile	0.79	0.86	0.76	0.83	0.68	0.82	0.93
99 percentile and higher	0.63	0.76	0.58	0.69	0.50	0.67	0.83
Conditions added in 2019 for model V23							
Substance abuse, moderate to severe	0.99	0.97	1.00	0.96	1.01	0.99	0.99
Substance abuse, mild	0.76	0.80	0.84	0.72	0.78	0.83	0.85
Reactive and unspecified psychosis	0.89	0.81	0.86	0.80	0.81	0.81	0.98
Personality disorder	0.91	0.82	0.75	0.81	0.88	0.79	1.00
Chronic kidney disease, Stage 3	0.93	0.97	1.01	0.96	0.94	0.95	0.97
Number of beneficiary years (in thousands)	852	781	305	337	826	9,662	290

Note: CMS–HCC (CMS–hierarchical condition category), V (version), LTI (long-term institutionalized), AMI (acute myocardial infarction), CHF (congestive heart failure), COPD (chronic obstructive pulmonary disease). V22, V23, and V24.1 are versions of the CMS–HCC model that CMS used in 2017 and 2018; 2019; and 2020, respectively. We define "number of conditions" for each beneficiary as the number of HCCs for that beneficiary. "Base-year cost" is the cost to fee-for-service Medicare for each beneficiary in the base year of our analysis, 2016. "Conditions added in 2019" are the HCCs that CMS added to the CMS–HCC model in 2019. "Number of beneficiary years" is the sum across all beneficiaries in our analytic file of the fraction of the prediction year (2017) that each beneficiary was in both Part A and Part B of fee-for-service Medicare.

Source: MedPAC analysis of the version of the CMS–HCC model that CMS used to risk adjust MA payments in 2017 and 2018. Data used in this analysis include all standard analytic claims files for the inpatient, outpatient, and physician sectors in 2016; standard analytic claims for all sectors in 2017; Medicare denominator files for 2016 and 2017; and the custom Medicare enrollment file.

TABLE 4–2

Predictive ratios for CMS–HCC model V23, which adds HCCs for substance abuse disorders, mental health disorders, and kidney disease

	Full Medicaid		Partial Medicaid		No Medicaid		
Beneficiary category	**Disabled**	**Aged**	**Disabled**	**Aged**	**Disabled**	**Aged**	**LTI**
R^2	0.124	0.117	0.081	0.106	0.080	0.123	0.096
Conditions in model V22							
AMI	1.02	0.99	0.99	1.00	0.98	1.00	1.02
Cancer	1.01	1.00	1.01	0.99	0.99	1.00	1.01
CHF	1.01	1.00	1.01	1.00	1.00	1.00	1.01
COPD	1.01	1.00	1.00	1.00	1.00	1.00	1.00
Diabetes	1.01	1.00	1.00	1.00	1.01	1.00	1.00
Mental illness	1.00	1.00	1.00	0.99	1.01	1.00	1.01
Schizophrenia	1.00	0.97	0.99	1.00	1.01	0.98	1.01
All stroke	0.99	0.98	1.02	0.98	0.98	0.99	1.01
Ischemic or unspecified stroke	0.99	0.97	1.01	0.98	0.98	1.00	1.00
Number of conditions (added in model V24.1)							
No conditions	0.83	0.90	0.89	0.92	0.86	0.96	0.81
1 condition	0.98	1.02	1.00	1.01	1.00	1.01	0.99
2 conditions	1.02	1.01	1.02	1.01	1.04	1.01	1.02
3 conditions	1.03	1.02	1.02	1.01	1.06	1.01	1.02
4 conditions	1.03	1.02	1.03	1.01	1.05	1.01	1.02
5 or more conditions	1.01	1.00	1.01	1.00	1.00	1.00	1.00
8 or more conditions	0.99	0.97	0.97	0.97	0.96	0.98	0.99
10 or more conditions	0.97	0.96	0.95	0.94	0.93	0.96	0.99
12 or more conditions	0.96	0.93	0.95	0.91	0.91	0.94	0.98
Percentile of base-year cost							
0 to 20 percentile	1.45	1.02	1.39	1.11	1.72	1.28	0.84
20 to 40 percentile	1.53	1.36	1.52	1.33	1.67	1.33	1.51
40 to 60 percentile	1.26	1.23	1.24	1.16	1.23	1.13	1.32
60 to 80 percentile	1.06	1.05	1.04	1.01	0.97	0.96	1.04
80 to 95 percentile	0.92	0.92	0.92	0.89	0.83	0.88	0.96
95 to 99 percentile	0.79	0.86	0.77	0.83	0.68	0.82	0.93
99 percentile and higher	0.63	0.76	0.58	0.69	0.50	0.67	0.83
Conditions added in 2019 for model V23							
Substance abuse, moderate to severe	1.00	0.98	1.01	0.97	1.03	0.99	0.99
Substance abuse, mild	0.95	0.94	1.06	0.86	1.03	1.00	0.85
Reactive and unspecified psychosis	0.97	0.98	0.99	1.00	1.00	0.99	0.99
Personality disorder	1.04	0.93	0.83	0.84	1.05	0.93	1.00
Chronic kidney disease, Stage 3	1.00	1.00	1.07	1.00	1.00	1.00	0.97
Number of beneficiary years (in thousands)	852	781	305	337	826	9,662	290

Note: CMS–HCC (CMS–hierarchical condition category), V (version), LTI (long-term institutionalized), AMI (acute myocardial infarction), CHF (congestive heart failure), COPD (chronic obstructive pulmonary disease). V22, V23, and V24.1 are versions of the CMS–HCC model that CMS used in 2017 and 2018; 2019; and 2020, respectively. We define "number of conditions" for each beneficiary as the number of HCCs for that beneficiary. "Base-year cost" is the cost to fee-for-service Medicare for each beneficiary in the base year of our analysis, 2016. "Conditions added in 2019" are the HCCs that CMS added to the CMS–HCC model in 2019. "Number of beneficiary years" is the sum across all beneficiaries in our analytic file of the fraction of the prediction year (2017) that each beneficiary was in both Part A and Part B of fee-for-service Medicare.

Source: MedPAC analysis of the version of the CMS–HCC model that CMS used to risk adjust MA payments in 2019. Data used in this analysis include all standard analytic claims files for the inpatient, outpatient, and physician sectors in 2016; standard analytic claims for all sectors in 2017; Medicare denominator files for 2016 and 2017; the custom Medicare enrollment file; and Medicare risk adjustment files for 2017.

Despite the improvement in performance for beneficiaries in the five HCCs added to V23, when we stratified beneficiaries by the number of conditions they had (a variable not in V23 but added to V24.1 by CMS), we found some degree of underprediction in all population segments for beneficiaries with no conditions (PR as low as 0.83 in the FULL_BENEFIT_DISABLED segment) and for beneficiaries with many conditions (PRs as low as 0.91 for the PARTIAL_BENEFIT_AGED and NONDUAL_DISABLED segments who have 12 or more conditions) (Table 4-2, p. 109).

We also caution that adding HCCs to the model can increase opportunities for MA plans to code more intensively to increase revenue, especially if the additional HCCs represent conditions that are diagnosed using relatively discretionary standards (meaning there is more than minimal provider discretion when assigning the code). The HCCs that CMS added for V23 can be considered discretionary. Previously, CMS addressed coding intensity by removing HCCs from the model that the agency suspected were being aggressively coded by plans, including HCCs for lower severity chronic kidney disease. Empirical analyses indicate that removal of these HCCs reduced the average risk scores of MA enrollees, suggesting that it helped offset the effects of coding intensity (Kronick and Welch 2014, Medicare Payment Advisory Commission 2019b). The decision by CMS to add Stage 3 chronic kidney disease to V23 reintroduces one of the HCCs that CMS had previously removed.

In summary, we found that V23 predicts costs well for each of the population segments of dually eligible beneficiaries and for groups of beneficiaries within those population segments who have conditions included in V23 (AMI, cancer, and so on), including the beneficiaries who have conditions in the five HCCs added to V23. However, V23 does not predict accurately when we group beneficiaries by variables that are not in V23: the number of conditions they have and their Medicare program spending in the base year. In addition, we are concerned that including the five HCCs may encourage plans to increase revenues through more intensive coding by coding more discretionary medical conditions.

Adding the number of medical conditions for each beneficiary improves cost prediction

For 2020, CMS made another change to the CMS–HCC model by adding the number of conditions for each beneficiary to model V23, which resulted in V24.1. CMS determined the number of conditions for each beneficiary as the number of HCCs that the beneficiary has in V24.1. For example, if a beneficiary had medical diagnoses that map to HCC 19 (diabetes without complications), HCC 85 (congestive heart failure), and HCC 111 (chronic obstructive pulmonary disease), CMS would determine this beneficiary has three medical conditions. CMS continued to produce separate estimates for the six community-based population segments. CMS did not add number of conditions for the institutional population, so we excluded that population from this part of our analysis.

The method we used to estimate the coefficients for V24.1 for each of the six population segments was similar to the method used by CMS. Important features of that method include:

- The number of conditions for a beneficiary is the number of HCCs indicated in the CMS–HCC model, not the number of HCCs in the full HCC model.
- We used 0/1 dichotomous variables for each number of conditions. That is, for the "one condition" category, beneficiaries who had one condition received a "1" and all other beneficiaries received a "0." For the "two conditions" category, beneficiaries who had two conditions received a "1" and all other beneficiaries received a "0," and so on.
- When we included the indicators for the number of conditions in our regression analysis, the categories representing fewer than four to six conditions—depending on the population segment—had negative coefficients. CMS had a similar finding.
- To be consistent with CMS, we excluded from V24.1 the indicators for the number of conditions that had negative coefficients. This approach resulted in the smallest indicator for number of conditions being four conditions for NONDUAL_AGED, five conditions for FULL_BENEFIT_DISABLED, PARTIAL_BENEFIT_DISABLED, PARTIAL_BENEFIT_AGED, and NONDUAL_DISABLED; and six conditions for FULL_BENEFIT_AGED.

Adding the number of conditions to the CMS–HCC model improves how well the model predicts costs for beneficiaries with no conditions and for those with many conditions (10 or more). For example, for the NONDUAL_DISABLED population segment (no Medicaid benefits, disabled), the PRs increased from 0.86

under V23 (Table 4-2, p. 109) to 0.94 under V24.1 for beneficiaries with no conditions (Table 4-3, p. 112), and from 0.91 under V23 (Table 4-2) to 0.94 under V24.1 for beneficiaries with 12 or more conditions (Table 4-3). Moreover, when we stratify beneficiaries by their program spending in the base year, V24.1 produces slightly better PRs relative to V23 for beneficiaries with very high levels of base-year costs (top 1 percent). Despite this slight improvement, PRs for this beneficiary group are still far from 1.00 under model V24.1.

Using two years of diagnosis data helps address coding intensity issues but slightly worsens cost prediction for beneficiaries with high spending

To date, CMS has not implemented a version of the CMS–HCC model that uses two years of beneficiaries' diagnosis data to determine their HCCs and risk scores rather than the single year of data that CMS has used for all CMS–HCC models, including those we evaluated in this report.

To evaluate the effects of using two years of diagnosis data, we applied two years of diagnosis data to model V24.1, calling it model V24.2. One caveat: We used the same beneficiary sample to evaluate V22, V23, and V24.1 (27.2 million FFS beneficiaries), but we used a subset of that sample to evaluate V24.2 (24.7 million FFS beneficiaries). The reason is that in a given year, the number of beneficiaries who have two years of diagnosis data is less than the number of beneficiaries who have one year of diagnosis data from the Medicare FFS claims we use in this analysis.

For most of the groups and population strata we evaluated, the PRs from V24.2 are similar to the PRs from V24.1. However, we found worse (lower) PRs under V24.2 relative to V24.1 for beneficiaries with high Medicare spending in the base year of 2016—above the 95th percentile (Table 4-4, p. 113).

The PRs for beneficiaries who had high base-year spending are worse when we use two years of diagnosis data because of a combination of two factors:

- The coefficients for most HCCs in the CMS–HCC model are lower when we use two years of data than when we use one year of data.
- Beneficiaries with high base-year spending often have a high number of HCCs.

For these beneficiaries, the lower coefficients on the HCCs under two years of data produce lower risk scores (which indicate lower predicted costs). For example, a beneficiary in our analytic file had 12 HCCs recorded under one year of data and 13 HCCs recorded under two years of data. These HCCs produced a risk score of 5.87 under one year of data and 5.10 under two years of data, a decrease of 0.77, even though this beneficiary had more HCCs under two years of diagnosis data. The coefficients on HCCs and, consequently, risk scores decline under two years of diagnosis data because using two years of data captures beneficiaries with less severe cases of a given condition. These less severe cases are less costly to treat, which results in lower coefficients on the related HCCs.

Despite the decrease in the PRs for beneficiaries who have high base-year Medicare spending when using two years of diagnosis data, we believe use of two years of diagnosis data would be beneficial for MA risk adjustment because it would decrease the extent of coding differences that persist between the MA and FFS sectors of the Medicare program. When we use only one year of diagnosis data, beneficiaries are likely to have more medical conditions recorded in their medical record if they are in MA than if they are in FFS Medicare. This discrepancy in coding between sectors does not mean that providers in the MA program or in the FFS program are improperly coding conditions. This discrepancy points to a difference in incentives between the two sectors. In the MA program, payments to plans are heavily dependent on the conditions that providers record for a beneficiary. Hence, MA plans have an incentive to encourage providers to code all the conditions that an enrollee has. In the FFS program, payment for services provided in physician offices or hospital outpatient departments largely depends on the services provided, while the conditions treated do not affect payment. At the same time, payment for services provided in the hospital inpatient setting depends on the patient's conditions, but in 2017, only 18.5 percent of FFS beneficiaries had at least one inpatient stay (Medicare Payment Advisory Commission 2019a). Hence, in most of the encounters that FFS beneficiaries have with health care providers, there is little incentive for providers to record all of a beneficiary's conditions.

The action of risk adjustment is to adjust the payment for each MA enrollee by the percentage that the enrollee would be expected to cost in FFS Medicare relative to the national average. That is, if an MA enrollee has demographic data and HCCs that indicate that the enrollee would cost 20 percent more in FFS Medicare than the

TABLE 4–3 **Predictive ratios for CMS–HCC model V24.1, which adds the number of conditions**

	Full Medicaid		Partial Medicaid		No Medicaid	
Beneficiary category	**Disabled**	**Aged**	**Disabled**	**Aged**	**Disabled**	**Aged**
R^2	0.124	0.118	0.081	0.106	0.081	0.123
Conditions in model V22						
AMI	1.03	0.99	0.99	1.01	0.98	1.00
Cancer	1.01	1.00	1.01	1.00	0.99	1.00
CHF	1.01	1.00	1.01	1.00	0.99	1.00
COPD	1.01	1.00	1.00	1.00	1.00	1.00
Diabetes	1.01	1.00	1.00	1.00	1.01	1.00
Mental illness	1.00	1.00	1.00	1.00	1.01	1.00
Schizophrenia	1.00	0.97	0.99	1.00	1.00	0.98
All stroke	0.99	0.99	1.02	0.99	0.97	0.99
Ischemic or unspecified stroke	0.99	0.97	1.02	0.99	0.98	0.99
Number of conditions (added in model V24.1)						
No conditions	0.92	0.92	0.94	0.96	0.94	0.98
1 condition	1.00	1.04	1.03	1.02	1.02	1.02
2 conditions	1.01	1.02	1.02	1.01	1.01	1.00
3 conditions	1.00	1.01	1.00	0.99	1.00	0.99
4 conditions	0.99	1.01	1.00	0.98	0.98	1.00
5 or more conditions	1.01	0.99	1.01	1.00	1.01	1.00
8 or more conditions	1.03	0.99	1.01	1.00	1.00	1.00
10 or more conditions	1.02	0.98	1.00	0.99	0.99	1.00
12 or more conditions	0.98	0.96	0.97	0.94	0.94	0.97
Percentile of base-year cost						
0 to 20 percentile	1.52	1.04	1.43	1.14	1.78	1.30
20 to 40 percentile	1.55	1.37	1.54	1.35	1.68	1.34
40 to 60 percentile	1.27	1.24	1.24	1.16	1.22	1.13
60 to 80 percentile	1.05	1.05	1.03	1.00	0.95	0.96
80 to 95 percentile	0.90	0.91	0.91	0.88	0.82	0.87
95 to 99 percentile	0.79	0.86	0.77	0.84	0.69	0.82
99 percentile and higher	0.65	0.77	0.59	0.70	0.51	0.68
Conditions added in 2019 for model V23						
Substance abuse, moderate to severe	1.00	0.98	1.01	0.99	1.01	0.99
Substance abuse, mild	0.95	0.94	1.06	0.88	1.01	1.00
Reactive and unspecified psychosis	0.97	0.98	0.99	1.01	0.99	0.99
Personality disorder	1.04	0.93	0.83	0.88	1.04	0.93
Chronic kidney disease, Stage 3	1.00	1.00	1.07	1.00	1.00	1.00
Number of beneficiary years (in thousands)	852	781	305	337	826	9,662

Note: CMS–HCC (CMS–hierarchical condition category), V (version), AMI (acute myocardial infarction), CHF (congestive heart failure), COPD (chronic obstructive pulmonary disease). V22, V23, and V24.1 are versions of the CMS–HCC model that CMS used in 2017 and 2018; 2019; and 2020, respectively. We define "number of conditions" for each beneficiary as the number of HCCs for that beneficiary. "Base-year cost" is the cost to fee-for-service Medicare for each beneficiary in the base year of our analysis, 2016. "Conditions added in 2019" are the HCCs that CMS added to the CMS–HCC model in 2019. "Number of beneficiary years" is the sum across all beneficiaries in our analytic file of the fraction of the prediction year (2017) that each beneficiary was in both Part A and Part B of fee-for-service Medicare.

Source: MedPAC analysis of version of the CMS–HCC model that CMS used to risk adjust MA payments in 2020. Data used in this analysis include all standard analytic claims files for the inpatient, outpatient, and physician sectors in 2016; standard analytic claims for all sectors in 2017; Medicare denominator files for 2016 and 2017; the custom Medicare enrollment file; and Medicare risk adjustment files for 2017.

TABLE 4–4

Predictive ratios for CMS–HCC model V24.2, a model created by the Commission for this analysis, which is based on two years of diagnosis data

	Full Medicaid		Partial Medicaid		No Medicaid		
Beneficiary category	**Disabled**	**Aged**	**Disabled**	**Aged**	**Disabled**	**Aged**	**LTI**
R^2	0.121	0.114	0.076	0.102	0.103	0.119	0.090
Conditions in model V22							
AMI	1.04	1.00	1.01	1.00	1.00	1.00	1.02
Cancer	1.00	1.00	1.01	1.00	1.00	1.00	1.01
CHF	1.01	1.00	1.00	1.00	1.00	1.00	1.01
COPD	1.00	1.00	1.00	1.00	1.00	1.00	1.00
Diabetes	1.01	1.00	0.99	1.01	1.00	1.00	1.00
Mental illness	1.00	1.00	1.00	1.00	1.00	1.00	1.04
Schizophrenia	1.00	0.98	0.99	1.00	1.02	0.99	1.01
Stroke	0.99	0.99	1.01	0.99	1.01	0.99	1.01
Ischemic or unspecified stroke	0.99	0.98	1.00	0.98	0.99	0.99	1.00
Number of conditions (added in model V24.1)							
No conditions	0.87	0.87	0.90	0.92	0.89	0.97	0.81
1 condition	0.96	1.02	1.00	1.03	1.01	1.01	0.99
2 conditions	1.00	1.02	1.01	1.02	1.01	1.01	1.02
3 conditions	1.02	1.01	1.00	1.00	1.03	1.00	1.02
4 conditions	1.01	1.01	1.01	0.99	1.02	1.00	1.02
5 or more conditions	1.01	1.00	1.00	1.00	1.00	1.00	1.00
8 or more conditions	1.01	0.99	1.00	1.00	1.00	1.00	0.99
10 or more conditions	1.04	0.98	1.00	1.00	1.02	0.98	0.99
12 or more conditions	0.99	0.94	0.97	0.94	0.96	0.94	0.97
Percentile of base-year cost							
0 to 20 percentile	1.53	1.04	1.45	1.15	1.82	1.31	0.86
20 to 40 percentile	1.56	1.38	1.54	1.36	1.72	1.35	1.53
40 to 60 percentile	1.29	1.26	1.27	1.21	1.26	1.15	1.36
60 to 80 percentile	1.08	1.09	1.06	1.03	0.99	0.94	1.09
80 to 95 percentile	0.91	0.92	0.90	0.88	0.83	0.86	0.96
95 to 99 percentile	0.75	0.81	0.71	0.78	0.66	0.77	0.89
99 percentile and higher	0.58	0.60	0.53	0.64	0.45	0.61	0.76
Conditions added in 2019 for model V23							
Substance abuse, moderate to severe	1.01	0.97	1.04	0.97	1.02	0.97	1.00
Substance abuse, mild	1.00	0.98	1.00	0.93	1.00	1.01	0.96
Reactive and unspecified psychosis	1.00	0.98	0.99	1.02	1.01	1.02	1.05
Personality disorder	0.98	0.89	0.88	0.91	1.07	0.94	1.03
Chronic kidney disease, Stage 3	1.02	0.99	1.09	1.00	1.02	0.98	1.01
Number of beneficiary years (in thousands)	760	692	272	310	724	8,811	272

Note: CMS–HCC (CMS–hierarchical condition category), V (version), LTI (long-term institutionalized), AMI (acute myocardial infarction), CHF (congestive heart failure), COPD (chronic obstructive pulmonary disease). V22, V23, and V24.1 are versions of the CMS–HCC model that CMS used in 2017 and 2018; 2019; and 2020, respectively, and V24.2 is a version of the CMS–HCC model that we created for this report. We define "number of conditions" for each beneficiary as the number of HCCs for that beneficiary. "Base-year cost" is the cost to fee-for-service Medicare for each beneficiary in the base year of our analysis, 2016. "Conditions added in 2019" are the HCCs that CMS added to the CMS–HCC model in 2019. "Number of beneficiary years" is the sum across all beneficiaries in our analytic file of the fraction of the prediction year (2017) that each beneficiary was in both Part A and Part B of fee-for-service Medicare.

Source: MedPAC analysis of versions of the CMS–HCC model that uses two years of diagnosis data to determine beneficiaries' conditions. Data used in this analysis include all standard analytic claims files for the inpatient, outpatient, and physician sectors in 2015 and 2016; standard analytic claims for all sectors in 2017; Medicare denominator files for 2016 and 2017; the custom Medicare enrollment file; and Medicare risk adjustment files for 2017.

national average, then the MA payment for that enrollee is adjusted upward by 20 percent. However, MA plans typically provide more complete coding of their enrollees' conditions than would be recorded on FFS claims. This more complete coding results in MA enrollees having higher risk scores than they would have if they were enrolled in FFS Medicare, which results in overpayments to MA plans.

The difference in "coding intensity" between the MA and FFS programs has been persistent. For example, the Commission found that 35 percent of FFS beneficiaries who had kidney failure recorded on a claim in 2007 did not have kidney failure recorded on a claim in 2008. In contrast, only 29 percent of MA enrollees who had kidney failure recorded in 2007 did not have kidney failure recorded in 2008 (Medicare Payment Advisory Commission 2012). However, if CMS uses two years of diagnosis data from FFS Medicare to estimate the CMS–HCC model, CMS will capture more conditions among the FFS population, and the profile of conditions among the FFS population will more closely match the profile of conditions that would have been recorded for those beneficiaries had they been in the MA program. The Commission has done analysis that indicates that use of two years of diagnosis data would reduce MA risk scores relative to FFS Medicare by 1 percent to 2 percent (Medicare Payment Advisory Commission 2016). The result would be reduced payment errors that occur because of coding differences between the MA and FFS programs.

Use of two years of data would also result in the CMS–HCC model producing more accurate estimates of the cost of having a given condition because two years of diagnosis data would identify more beneficiaries who have that condition. Use of one year of data typically identifies the more severe, higher cost cases for a given condition and misses the less severe, lower cost cases. Use of two years of data identifies more of these lower cost cases, which would produce more accurate representations of the cost of each condition in the CMS–HCC model.

Summary

In this chapter, we have reported how each of the changes to the CMS–HCC model required by the 21st Century Cures Act has affected the predictive accuracy of the model. Our results indicate that each of the changes improves the predictive accuracy for each of the beneficiary populations that are the focus of the changes:

- Creating separate versions of the model for partial Medicaid beneficiaries and full Medicaid beneficiaries produces accurate predictions of the cost of these beneficiaries.
- Adding indicators for mental health disorders, substance abuse disorders, and chronic kidney disease improves how well the CMS–HCC model predicts the cost of beneficiaries who have these conditions, although adding such indicators may provide additional opportunities for MA plans to increase revenue by coding more intensively.
- Adding measures of the number of conditions for each beneficiary improves how well the CMS–HCC model predicts the cost of beneficiaries who have 10 or more conditions.

We note that all versions of the CMS–HCC model that we evaluated overpredict the costs of beneficiaries with low Medicare costs in the base year and underpredict the costs of beneficiaries with very high Medicare costs in the base year. These prediction errors at the extremes of the distribution of base-year costs could be an issue for future consideration.

We found that using two years of diagnosis data to determine beneficiaries' conditions produces payment adjustments that are about as accurate as using one year of diagnosis data, though it produces larger underpayments for those with high levels of Medicare spending than using one year of diagnosis data. Nevertheless, in our view, the use of two years of diagnosis data would be beneficial for MA risk adjustment because it would decrease the extent of coding differences that persists between the MA and FFS sectors of the Medicare program. The result would reduce payment errors that occur because of coding differences between MA and FFS.

The Commission commends the progress that CMS has made in implementing the changes to the CMS–HCC model mandated by the 21st Century Cures Act. We encourage CMS to continue its work on this issue to complete the requirements by the mandated date of January 1, 2022. ■

Endnotes

1 A delay in payment adjustment under a concurrent model could occur for any condition diagnosed, depending on how the entity that operates the risk adjustment model chooses to implement the model. For example, risk adjustment under the Affordable Care Act of 2010 (ACA) uses a concurrent system and does not adjust payments for conditions diagnosed in a given year until the following year. For example, the ACA risk adjustment model would not use conditions diagnosed in 2019 to adjust payments until 2020.

2 The R^2 statistics are similar across these seven segments, ranging from 0.080 for PARTIAL_BENEFIT_DISABLED to 0.123 for FULL_BENEFIT_DISABLED. The R^2 did not change much as we evaluated the other versions in this study.

3 CMS has determined that the full HCC model has 122 HCCs that represent chronic conditions (Centers for Medicare & Medicaid Services 2018, Centers for Medicare & Medicaid Services 2017). At the same time, V22 of the CMS–HCC model has 79 HCCs, so V22 does not adjust payments for chronic conditions that are in 43 HCCs.

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CHAPTER 5

Realigning incentives in Medicare Part D

RECOMMENDATIONS

5-1 The Congress should make the following changes to the Part D prescription drug benefit:

- Below the out-of-pocket threshold:
  - Eliminate the initial coverage limit.
  - Eliminate the coverage-gap discount program.
- Above the out-of-pocket threshold:
  - Eliminate enrollee cost sharing.
  - Transition Medicare's reinsurance subsidy from 80 percent to 20 percent.
  - Require pharmaceutical manufacturers to provide a discount equal to no less than 30 percent of the negotiated price for brand drugs, biologics, biosimilars, and high-cost generic drugs.

COMMISSIONER VOTES: YES 16 • NO 0 • NOT VOTING 1 • ABSENT 0

5-2 Concurrent with our recommended changes to the benefit design, the Congress should:

- Establish a higher copayment amount under the low-income subsidy for nonpreferred and nonformulary drugs.
- Give plan sponsors greater flexibility to manage the use of drugs in the protected classes.
- Modify the program's risk corridors to reduce plans' aggregate risk during the transition to the new benefit structure.

COMMISSIONER VOTES: YES 16 • NO 0 • NOT VOTING 1 • ABSENT 0

5-3 Concurrent with our recommended changes to the benefit design, the Secretary should:

- Allow plans to establish preferred and nonpreferred tiers for specialty-tier drugs.
- Recalibrate Part D's risk adjusters to reflect the higher benefit liability that plans bear under the new benefit structure.

COMMISSIONER VOTES: YES 16 • NO 0 • NOT VOTING 1 • ABSENT 0

CHAPTER 5

Realigning incentives in Medicare Part D

Chapter summary

Medicare pays competing private plans to deliver drug benefits to enrolled beneficiaries under Part D. Medicare's payment system for Part D is different from fee-for-service (FFS) payment systems used under Part A and Part B. For Part D, policymakers envisioned a program that relies on competition among private plan sponsors that bear insurance risk for managing prescription drug use and spending while offering benefit packages that are attractive to enrollees. Instead of setting payments to plans administratively, Medicare's payments are based on bids submitted by plan sponsors that reflect their average cost (including administrative expenses and an operating margin) of providing a basic outpatient drug benefit to an enrollee of average health.

In the early years of the Part D program, plan sponsors were at risk for a large share of their enrollees' benefit spending, but that share has declined markedly over time. Between 2007 and 2017, among enrollees without Part D's low-income subsidy (LIS), the share of basic benefit costs for which plan sponsors were responsible declined from 53 percent to 29 percent. For LIS enrollees, plan liability decreased from 30 percent to 19 percent over the same period. Meanwhile, the Medicare program's share of benefits reimbursed through two cost-based mechanisms—reinsurance (intended to give plan sponsors some protection against unpredictable variation in costs) and low-income cost-sharing subsidies—rose commensurately. The magnitude of decreases in plans' share of benefit liability raises significant concerns because it shifts

In this chapter

substantial financial risk to the Medicare program and taxpayers and undermines a key feature of the Part D program: providing incentives for competing private plans that bear insurance risk for their enrollees' spending to negotiate prices with pharmacies and pharmaceutical manufacturers.

In 2016, the Commission recommended major changes to Part D's benefit structure that would have plan sponsors bear more financial risk for their enrollees' drug spending while, at the same time, providing sponsors with greater flexibility to use formulary tools. The Commission believed that the recommendations would introduce better incentives for plan sponsors to manage drug benefit spending. Since then, changes in law and expanded use of high-priced drugs have further eroded the competitive incentives for cost control and have led the Commission to consider new approaches for restructuring Part D.

Building on the 2016 recommendations, the Commission recommends changes to the Part D program that would restore the role of risk-based, capitated payments that was present at the start of Part D, limit enrollees' out-of-pocket (OOP) spending, and eliminate features of the program that distort market incentives. These reforms will better align the incentives in Part D with the interests of the Medicare program and its beneficiaries. The Commission's package of recommendations would restructure Part D's defined standard benefit as follows:

- For spending below the catastrophic threshold, eliminate the manufacturers' coverage-gap discount that currently applies to enrollees without the LIS and remove the coverage gap for LIS enrollees. These changes would create a standard benefit for all enrollees in which plans would become responsible for 75 percent of spending for benefits between the deductible and the catastrophic threshold, with enrollees responsible for the remaining 25 percent through cost sharing.
- For spending above the catastrophic threshold, reduce Medicare's reinsurance by shifting insurance risk to plan sponsors and drug manufacturers. Medicare would provide 20 percent reinsurance rather than the current 80 percent. Manufacturers would become responsible for at least 30 percent of catastrophic spending on high-priced medicines, while plan sponsors would be liable for the remaining 50 percent. That share is up from the 15 percent of catastrophic benefits that plans cover today. Consistent with our 2016 recommendations, the policy would provide enrollees with greater financial protection by adding an annual cap on beneficiaries' OOP costs.

We recommend that the reduction in Medicare's reinsurance payments and increase in plan liability for catastrophic spending be phased in. (The other elements of

the new benefit structure—eliminating the coverage gap, replacing the coverage-gap discount program with a new discount program in the catastrophic phase, and adding an annual cap on beneficiary OOP costs—would be implemented without a transition.) A longer transition would give plans more time to adjust to the new benefit structure and distribution of risk and allow policymakers to respond to any unexpected outcomes before the new structure is fully phased in. However, it would also leave some of the current system's misaligned incentives in place longer and potentially inhibit the entrance into the market of new Part D sponsors.

Under the new benefit structure, sponsors would incorporate lower expected Medicare reinsurance subsidies and higher expected benefit liability into plan bids. In turn, Medicare's capitated payments to plans would increase to incorporate their new, higher share of spending below and above the catastrophic threshold. CMS would also apply risk adjusters to reflect predictable differences in average spending among enrollees based on factors such as age category, disability status, LIS status, and diagnoses.

We recommend a new manufacturers' discount of at least 30 percent in the catastrophic phase of the benefit. The discount would be more likely to apply to drugs and biologics that command high prices, which could act as a drag on price growth. The discount would apply to LIS beneficiaries as well as to enrollees without the LIS. In addition, the discount could be structured so that if the average price of drugs that were subject to the discount increased faster than a benchmark (such as average Part D spending), the discount rate would increase commensurately.

To help plan sponsors manage overall drug spending more effectively, we recommend that the Congress establish a higher copayment amount under the LIS for nonpreferred and nonformulary drugs. Current LIS copayments provide much weaker financial incentives to choose lower cost medications than those faced by other enrollees. In addition, we recommend that plan sponsors be provided with greater formulary flexibility for drugs in the protected classes. Currently, plan sponsors' inability to exclude products from a plan's formulary limits sponsors from using competitive pressure among alternative drug therapies to negotiate manufacturer rebates. We also recommend that plans be allowed to establish preferred and nonpreferred tiers for specialty-tier drugs to encourage their enrollees to use lower priced therapies.

It will be critically important for CMS to recalibrate Part D's risk adjustment model to reflect the increased plan liability. The Commission's recommended reforms would result in higher capitated payments for all enrollees, with a larger impact,

in dollar terms, for LIS beneficiaries. Given the structure of the risk adjustment model, we believe that CMS will be able to recalibrate the model to ensure that overall payment rates are adequate for both LIS enrollees and other Part D beneficiaries. Nevertheless, one concern is that because risk adjustment models tend to underpredict very high spending and overpredict very low spending, plans that enroll a relatively large share of high-cost beneficiaries could be disadvantaged. Of particular concern to the Commission are smaller plan sponsors that enroll a high share of LIS beneficiaries.

To examine whether plan sponsors with high shares of LIS beneficiaries are likely to be disadvantaged as a result of inadequate risk adjustment, we compared variation in Part D's gross drug spending for LIS and other Part D beneficiaries. Our findings suggest that, because spending for LIS beneficiaries has relatively less variation than spending for beneficiaries without the LIS, CMS's risk-adjusted payments are less likely to systematically underestimate actual spending for LIS enrollees with very high costs than for other high-cost enrollees. We also separately examined variation in catastrophic spending, which is less easily predicted than spending in the lower phases of the benefit because the extreme values are influenced more heavily by use of high-priced drug and biologic treatments for less-prevalent conditions, such as cancer and rheumatoid arthritis. We found that relative variation around the average was more than twice as large for beneficiaries without the LIS compared with LIS beneficiaries. This difference suggests a recalibrated risk adjustment model would be more likely to underpredict very high spending incurred by beneficiaries without the LIS than it would for beneficiaries with the LIS.

Given plans' greater insurance risk associated with catastrophic spending under these reforms, policymakers could consider modifying the Part D risk corridors to temporarily provide plan sponsors with greater protection during a transition to the new benefit structure. For example, the risk corridors could be narrowed so that plans were fully at risk for less than 5 percent of their aggregate expected benefit costs. Policymakers could also consider different risk-sharing percentages in the corridors, potentially increasing plans' aggregate stop-loss protection (i.e., reducing plans' insurance risk above a threshold). While the enhanced protection would be available to all plans, in practice, the protection would be particularly valuable for smaller plans and plan sponsors that do not have the scale to spread the insurance risk or the capital to reinsure themselves. ■

Background

In 2016, the Commission recommended major changes to the structure of Medicare's Part D prescription drug benefit to address the misaligned incentives as reflected in patterns of Medicare payments to private plans and plans' bidding behavior. Those recommendations would have had plan sponsors bear more financial risk for their enrollees' drug spending while, at the same time, providing sponsors with greater flexibility to use formulary tools (Medicare Payment Advisory Commission 2016).

Since then, changes in law and greater spending for high-priced drugs have led the Commission to consider new approaches for restructuring Part D (Medicare Payment Advisory Commission 2019d). The reforms we recommend in this chapter build on the 2016 package of recommendations, but with two major changes. First, for spending below the catastrophic threshold, we recommend eliminating the manufacturers' coverage-gap discount that currently applies to enrollees without the low-income subsidy (LIS) and removing the coverage gap for LIS enrollees. These changes would create a standard benefit for all enrollees in which plans would become responsible for 75 percent of benefits between the deductible and the catastrophic threshold, with enrollees responsible for the remaining 25 percent through cost sharing. Second, for spending above the catastrophic threshold, we recommend shifting insurance risk from Medicare to plan sponsors and drug manufacturers. Medicare would provide 20 percent reinsurance rather than the current 80 percent. Manufacturers would become newly responsible for 30 percent or more of catastrophic spending on high-priced medicines, while plan sponsors would be liable for the remaining 50 percent, up from the 15 percent of catastrophic spending they cover today. Consistent with our 2016 recommendations, we also recommend providing enrollees with greater financial protection by adding an annual cap on beneficiaries' out-of-pocket (OOP) costs.

This chapter also provides an overview of ways in which the program could give plan sponsors greater flexibility to manage formularies, as well as how Part D's mechanisms for sharing risk might be modified during the transition to a restructured benefit.

Misaligned incentives under Medicare's payment system for Part D

Medicare's payment system for Part D is different from fee-for-service (FFS) payment systems used under Part A and Part B. For Part D, policymakers envisioned a program that relies on competition among private plan sponsors that bear insurance risk for managing prescription drug use and spending while offering benefit packages that are attractive to enrollees. Part D subsidizes basic drug benefits whether a beneficiary is in FFS Medicare and enrolls in a stand-alone prescription drug plan (PDP) or in Medicare Advantage (MA) and enrolls in an MA–Prescription Drug [plan] (MA–PD). Instead of setting payments to plans administratively, Medicare's payments are based on bids submitted by plan sponsors that reflect their average cost (including administrative expenses and an operating margin) of providing a basic outpatient drug benefit to an enrollee of average health (Medicare Payment Advisory Commission 2019c). Part D includes risk corridors that limit each plan's overall losses or profits if a plan's benefit spending is substantially higher or lower than amounts anticipated in the plan's bid. If plan sponsors are successful at keeping benefit costs below what they bid, they retain most of the difference between payments and actual benefit costs as additional profits. The philosophical foundation of using competing private plans in Part D is reflected in the law's "noninterference" provision, which explicitly prohibits the Health and Human Services Secretary from "interfer[ing] with the negotiations between drug manufacturers and pharmacies and PDP sponsors." The law also prohibits the Secretary from "requir[ing] a particular formulary or institut[ing] a price structure for the reimbursement of covered Part D drugs." (See text box on the Commission's approach to date with respect to Part D reforms, p. 124.)

Medicare law defines a standard Part D benefit that, for 2020, includes a $435 deductible and 25 percent coinsurance until the enrollee reaches an OOP threshold (at roughly $9,000 to $10,000 in gross drug spending).[1] Above this threshold, enrollees generally pay 5 percent coinsurance with no upper limit on their annual cost-sharing liability. Most plan sponsors structure their basic benefits in ways that differ from the defined standard benefit, but sponsors must demonstrate that those alternative benefit structures have the same average value as the defined standard benefit. Medicare provides two types of subsidies to plans on behalf of all Part D enrollees: (1) monthly capitated payments adjusted for risk and (2) individual reinsurance equal to 80 percent of prescription costs above the OOP threshold (net of postsale rebates). Medicare's subsidies aim to cover 74.5 percent of the cost of basic benefits, with enrollee

The Commission's approach to Part D reform

Policymakers structured the Part D program using private plans that compete to attract enrollees based on the prescription drugs they cover, pharmacy networks, premiums, cost sharing, and quality of services. Plan sponsors negotiate with pharmacies over reimbursement rates for prescriptions filled by their enrollees, as well as with pharmaceutical manufacturers for postsale rebates. Under current Part D law, the federal government may not interfere in those private negotiations, establish a specific formulary, or set prices for drugs.

To date, the Commission has not recommended measures that would require altering this basic approach. In keeping with the program's original philosophy, the Commission's 2016 recommendations would modify the benefit design and structure of Medicare subsidies to strengthen the incentives of private entities involved in negotiating drug prices (Medicare Payment Advisory Commission 2016). Similarly, our recommendations in this chapter aim to restore the role of risk-based, capitated payments that was present at the start of Part D and eliminate features of the program that distort market incentives.

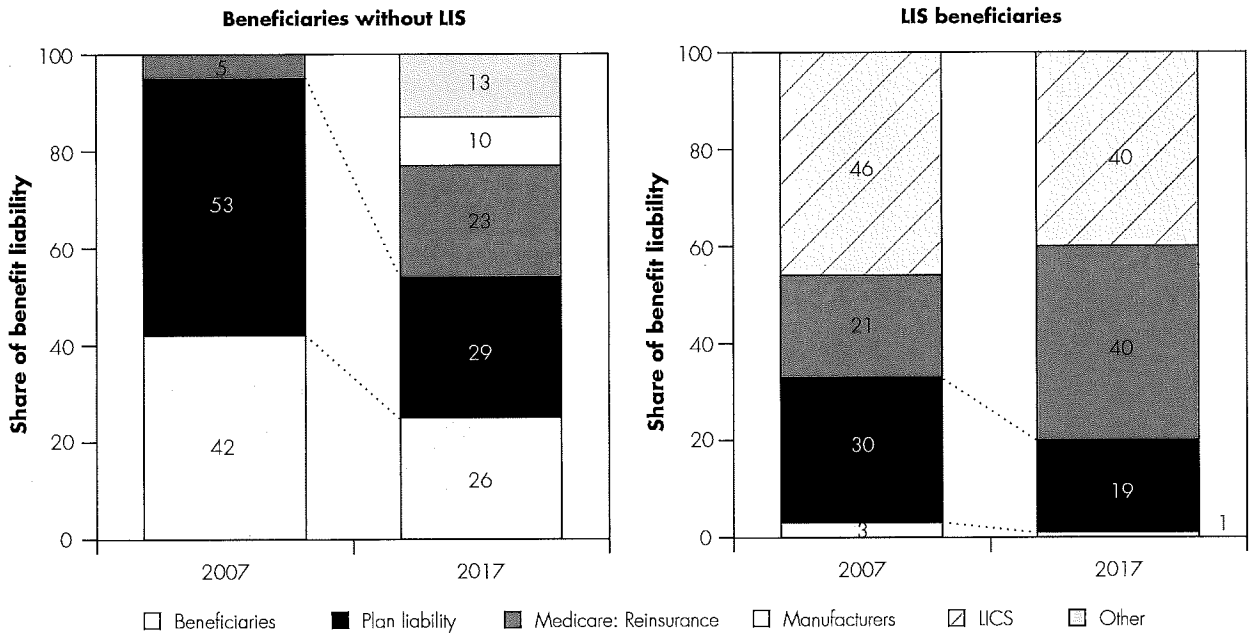
Nevertheless, the Commission intends to continue monitoring growth in drug prices and monitoring the implications of that growth for beneficiaries' access to biopharmaceutical therapies and for taxpayers. The premise behind Part D's competitive approach is that plan sponsors can negotiate for lower prices because manufacturers are offering competing drug therapies. In therapeutic classes where such competition is weak or does not exist, private plans have little or no bargaining leverage with manufacturers for price reductions. Other policy approaches may be needed to address those circumstances. ■

premiums covering the remaining 25.5 percent. Premiums for plans vary individually, however, depending on how high or low their sponsor bids and whether they offer supplemental coverage (which Medicare does not subsidize).

The Part D benefit also includes the LIS to ensure that poorer beneficiaries have sufficient access to drug coverage. Beneficiaries qualify for the LIS if they are eligible for any type of Medicaid benefits or have income below 150 percent of the federal poverty guideline and limited assets.[2] In 2019, 28 percent of Part D enrollees received the LIS, most of whom were Medicare–Medicaid dual-eligible beneficiaries. Part D's LIS has two components: premium subsidies and cost-sharing subsidies. The low-income cost-sharing subsidy (LICS) makes up more than 85 percent of combined LIS spending. CMS makes monthly prospective payments to plans for both LIS premium subsidies and the LICS. Payments for the latter are based on plan estimates and are later reconciled to actual costs after the end of each plan year.

In keeping with Part D's market-based approach, in the early years of the program, plan sponsors were at risk for a large share of their enrollees' benefit spending. However, over the past decade, the share of benefit costs borne by plan sponsors has declined markedly. Figure 5-1 displays estimates of Part D spending, net of rebates, for basic benefits for enrollees with and without the LIS. The estimates reflect spending amounts on Part D claims minus average rebates as reported by the Medicare Trustees (Boards of Trustees 2019). Between 2007 and 2017, among enrollees without the LIS, the share of basic benefit costs for which plan sponsors were responsible declined from 53 percent to 29 percent. For LIS enrollees, plan liability decreased from 30 percent to 19 percent over the same period. Meanwhile, the Medicare program's share of benefits reimbursed through two cost-based mechanisms—reinsurance and LICS—rose commensurately. The magnitude of decreases in plans' share of benefit liability raises significant concerns because it undermines key features of the Part D program: competing private entities that bear financial risk for their enrollees' spending.

FIGURE 5-1 **Plans' share of benefit liability declined markedly between 2007 and 2017**



Note: LIS (low-income subsidy), LICS (low-income cost-sharing subsidy). Estimated spending net of all rebates and discounts. Figures assume that the percentage reduction in total spending attributable to rebates and discounts does not differ systematically between beneficiaries with the LIS and those without the LIS. Components may not sum to 100 percent due to rounding. The "other" figures include payments by patient assistance organizations and third-party payers, other than Part D plans, that reduce beneficiary cost-sharing liability (such as employers who provide supplemental coverage to retirees).

Source: MedPAC based on Part D prescription drug event data and aggregate direct and indirect remunerations from the Medicare Trustees (Boards of Trustees 2019).

Low plan liability and expanded use of high-cost medicines have eroded incentives to manage spending

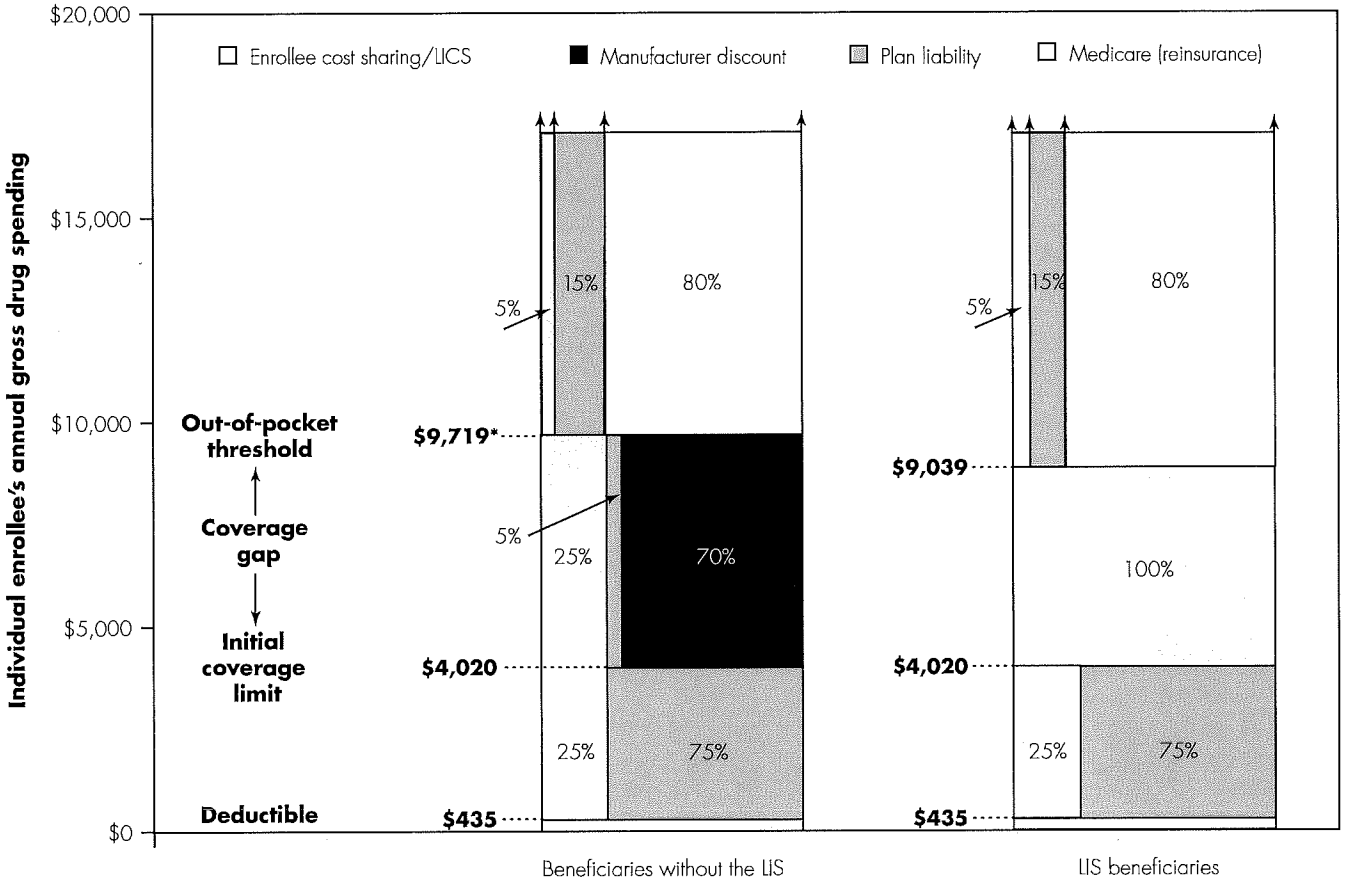
Changes in Part D law that financed the phase-out of the coverage gap through brand manufacturer discounts and the expanded use of high-cost medicines have reduced plans' liability for benefit spending, thereby eroding plans' incentives to manage spending.

Changes to Part D's coverage gap

Part D's defined standard benefit covers 75 percent of drug spending above the deductible and all but 5 percent coinsurance once an enrollee reaches the OOP threshold (Figure 5-2, p. 126). That threshold is based on "true OOP" costs because it excludes beneficiary cost sharing paid by most sources of supplemental coverage, such as employer-sponsored policies and enhanced benefits. For LIS enrollees, Medicare's LICS pays for the difference between the cost-sharing amounts in the plan's formulary and nominal copayments set by law (Figure 5-2).

Before 2011, enrollees who did not receive the LIS and had spending that exceeded an initial coverage limit were responsible for paying each subsequent prescription's full price at the pharmacy (i.e., 100 percent cost sharing) until they reached the OOP threshold. This is known as the coverage gap. Even today, when the defined standard benefit has 25 percent coinsurance in both the initial coverage phase and coverage-gap phase, many Part D plans structure their cost sharing differently across the two phases, with copayments for generics and preferred drugs initially, but 25 percent coinsurance in the coverage gap. For LIS enrollees, Part D's LICS pays for all coverage-gap spending other than nominal copayments set by law.

FIGURE 5–2 **Part D has two distinct benefit structures for enrollees with and without the LIS**



Note: LIS (low-income subsidy), LICS (low-income cost-sharing subsidy). For beneficiaries without the LIS (left bar), the coverage gap (between the initial coverage limit and the out-of-pocket (OOP) threshold) is depicted as it would apply to brand-name drugs. Plan sponsors pay 75 percent of the cost of generic prescriptions filled in the coverage-gap phase for beneficiaries without the LIS. For LIS beneficiaries, Medicare's low-income cost-sharing subsidy pays for all spending in the coverage gap except LIS enrollees' nominal copayments. In 2018, the total amount of cost sharing paid directly OOP by LIS beneficiaries accounted for about 1 percent of total gross spending.
*Total covered drug spending at the annual OOP threshold for beneficiaries who do not receive the LIS depends on the mix of brand and generic drugs filled in the coverage gap. The dollar amount shown ($9,719) was estimated by CMS for an individual with an average mix of drugs who does not receive Part D's LIS and has no other supplemental coverage.

Source: MedPAC depiction of Part D benefit structure for 2020 as set by law.

Manufacturer discounts in the coverage gap distort market incentives The Affordable Care Act of 2010 (ACA) and the Bipartisan Budget Act (BBA) of 2018 expanded Part D's defined standard benefit to gradually eliminate the coverage gap for enrollees without the LIS. As shown in Figure 5-2, this expansion left two distinct benefit structures in Part D: one for enrollees without the LIS and one for enrollees with the LIS. Much of this benefit expansion was financed by requiring brand-name drug manufacturers to discount prices in the coverage gap. While the phase-out of the coverage gap lowered OOP costs for some beneficiaries, the manufacturer discount artificially lowered the price of brand-name drugs relative to generics, reducing incentives to use generics.

Those incentives are further undermined because the 70 percent manufacturer coverage-gap discount on brand-name drugs is treated as though it were the enrollee's own spending. Thus, enrollees without the LIS reach

Part D's catastrophic phase more quickly when they use brand-name drugs than when they use generic drugs. Manufacturers of brand-name drugs benefit when enrollees reach the catastrophic phase because they are no longer required to discount prices.

Plan sponsors must cover 75 percent of generic spending but just 5 percent of brand spending in the coverage gap while also receiving postsale rebates and discounts on some brand prescriptions. Sponsors cover 15 percent of all spending (generic or brand) in the catastrophic phase. CMS's Office of the Actuary projects that, in 2020, plan sponsors will obtain postsale rebates and discounts worth about 28 percent of total drug costs (Boards of Trustees 2019). For some brand-name drugs, the value of rebates and discounts can exceed plan liability in both the coverage-gap and catastrophic phases of the benefit. For some products, plan sponsors may find that including a brand-name drug on their formulary rather than a generic or giving the brand preferred status lowers their plan liability. However, those formulary placement decisions also increase costs for enrollees and Medicare (Dusetzina et al. 2019). CMS raised concern about the effects of the coverage-gap discount and low plan liability in two recent call letters to plan sponsors (Centers for Medicare & Medicaid Services 2019a, Centers for Medicare & Medicaid Services 2018a).

Benefit design for LIS enrollees creates little incentive for cost control For LIS enrollees, the ACA retained Part D's original defined standard benefit structure, with no plan liability in the coverage-gap phase and no brand discount from manufacturers. Instead, coverage-gap costs are borne almost entirely by the Medicare program. Part D's LICS reimburses plan sponsors for the difference between 100 percent cost sharing and LIS enrollees' nominal copayments. Because 100 percent of the costs in the coverage gap count toward the OOP threshold, LIS beneficiaries reach the catastrophic phase of the benefit at a lower level of spending than other enrollees do.

The LIS benefit structure shares a common feature with the benefit design for other enrollees in that plan sponsors bear little or no liability for spending in the coverage-gap phase. For LIS enrollees, plans bear zero benefit liability, yet sponsors receive postsale rebates on some brand-name prescriptions. That means brand prescriptions filled by LIS enrollees in the coverage gap can be profitable for plan sponsors, undermining incentives for cost control. At the same time, because Medicare's LICS covers most cost sharing, LIS beneficiaries have little incentive to use lower cost drugs. These features may be reasons why LIS enrollees use more brand-name drugs even when generic alternatives are available.

Expanded role of high-priced drugs drives growth in reinsurance

Part D's distribution of drug spending has changed dramatically since the start of the program in 2006. Early on, the vast majority of spending was attributable to prescriptions for widely prevalent conditions such as high cholesterol, diabetes, and hypertension (Medicare Payment Advisory Commission 2010). Most prescription spending was for small-molecule brand-name drugs that competed with other therapies based on clinical effectiveness and price.

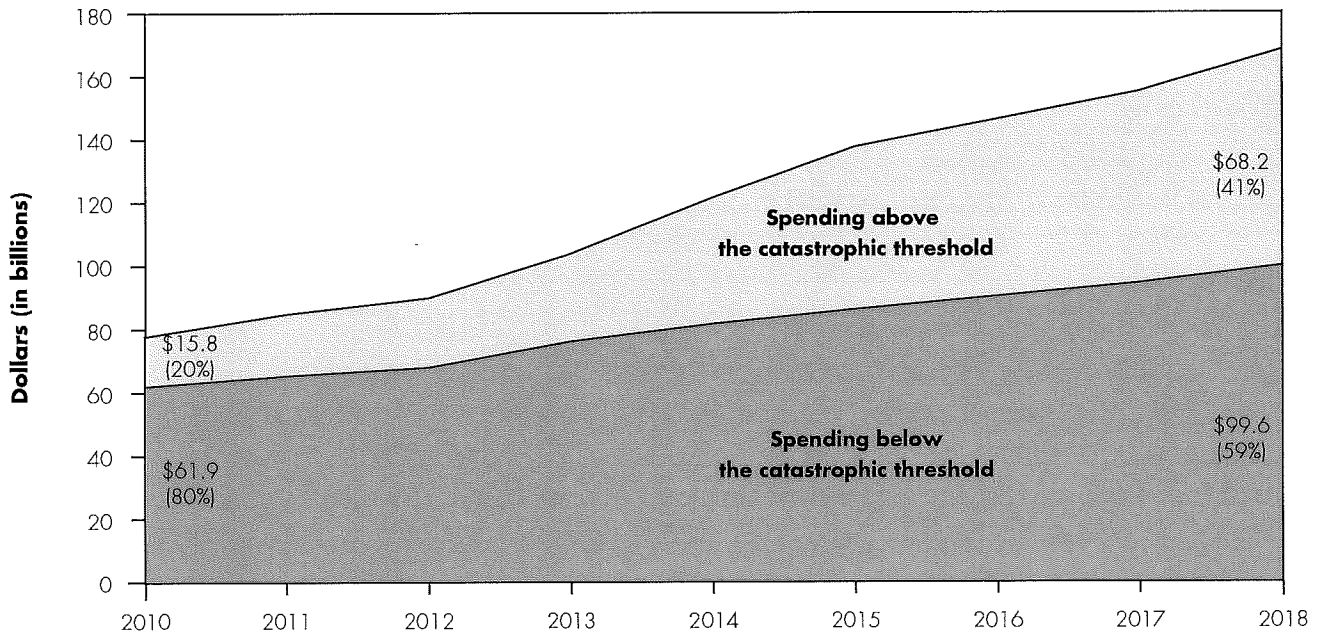
Beginning around 2010, a number of blockbuster treatments began to lose patent protection, and many Part D enrollees switched to generic versions of their medicines (Medicare Payment Advisory Commission 2017). As revenues for small-molecule brand-name drugs fell, manufacturers turned to developing orphan drugs, biologics, and other specialty drugs that treat smaller patient populations for conditions such as rheumatoid arthritis, hepatitis C, and cancer. Those medicines are often launched at very high prices, with annual costs per person sometimes reaching tens of thousands of dollars or more. List prices for many existing brand-name therapies increased at a rapid pace as well.

By law, CMS increases Part D's OOP threshold annually at the same rate as the annual change in enrollees' average drug expenses. Between 2006 and 2018, increased generic use helped to keep growth in average Part D drug expenses to about 4 percent per year (Medicare Payment Advisory Commission 2019e). However, prices of brand-name drugs and biologics grew at a much faster rate over the same period—more than 7 percent annually.[3] As a result, an increasing share of spending for high-priced, brand-name products is in Part D's catastrophic phase, where Medicare pays 80 percent of the costs through reinsurance and plans bear just 15 percent benefit liability.

Before 2010, less than 20 percent of spending was for prescriptions filled in the catastrophic phase of the Part D benefit. Since 2010, catastrophic spending has more than quadrupled. As a result, catastrophic spending's share of total spending increased from 20 percent in 2010 to 41 percent in 2018 (Figure 5-3, p. 128).

FIGURE 5-3

The proportion of gross Part D spending made up by catastrophic benefits more than doubled, 2010–2018



Note: Catastrophic benefits are defined as enrollee spending above Part D's out-of-pocket threshold. "Gross Part D spending" refers to amounts paid at the pharmacy before postsale rebates and discounts.

Source: MedPAC analysis of Part D prescription drug event data.

Higher prices, reflecting both increases in prices of existing products and the use of new high-priced drugs, are the primary driver of the rapid growth in catastrophic spending. Between 2010 and 2017, the average price per standardized, 30-day prescription filled by beneficiaries who reached the catastrophic phase grew by 9.4 percent per year, while the number of prescriptions filled per enrollee remained flat. This growth rate is in stark contrast to enrollees who did not reach the catastrophic phase: Their average price per prescription fell by an annual rate of 2.9 percent, while the number of prescriptions filled per enrollee grew by 1.3 percent per year.

Part D's benefit design contributes to the inflationary trend in drug prices

While Medicare's influence on drug pricing is indirect, the program accounts for about one-third of U.S. retail pharmaceutical sales (Hartman et al. 2019). As a result, Medicare's payment policies can have a significant financial effect on drug manufacturers. High drug prices are not unique to Part D. However, for medications that are more likely to be used by Medicare beneficiaries, the Commission has been concerned that the program's orientation toward premium competition and Part D's unique benefit design may contribute to higher prices (Medicare Payment Advisory Commission 2017).

One concern is that Part D plan sponsors' focus on rebates has been inflationary. In drug classes that have competing therapies, plan sponsors negotiate with brand manufacturers for rebates that are paid after a prescription has been filled. Generally, manufacturers pay larger rebates when a plan sponsor positions a drug on its formulary in ways that increase the likelihood that the manufacturer will win market share over competitors. Rebates are often calculated as a percentage of a drug's

list price, and thus higher prices can lead to a higher dollar amount of rebates. Moreover, when plan sponsors negotiate a "price protection" provision, rebates are linked directly to manufacturers' price increases (Kaczmarek 2015, Pharmacy Benefit Management Institute 2017). Sponsors may be less resistant to manufacturers' price increases for brand medications when there are rebates to offset some or all the plan's benefit liability.

In many situations, plan sponsors focus on rebates to keep their premiums competitive; they generally use rebate revenues to offset aggregate benefit costs and thereby lower their premiums. Using rebates to offset the cost of aggregate benefits may also increase the likelihood of retaining profits in Part D's risk corridors (Walker and Weaver 2019). However, beneficiaries pay coinsurance based on point-of-sale (POS) prices—those prices at the pharmacy counter before postsale rebates and discounts. In turn, beneficiaries reach Part D's OOP threshold more quickly than if coinsurance were charged on net prices. Similarly, the Medicare program pays more in reinsurance and LICS than it would if there were a smaller difference between POS and net prices (Centers for Medicare & Medicaid Services 2017).

Part D's unique structure can also contribute to inflationary trends in drug prices. Part D's benefit design can create incentives to include high-cost, high-rebate drugs on formularies over other drugs because plan sponsors bear relatively little liability for benefit spending in the coverage gap and catastrophic phase (Fein 2020). At the same time, manufacturers may find that, for some products, higher prices allow them to offer larger rebates than their competitors and gain more market share through favorable formulary placement.

In addition, because coverage-gap discounts apply to a limited range of spending (between the initial coverage limit and the OOP threshold), a manufacturer's liability for any given beneficiary is capped. In 2020, the maximum amount any brand manufacturer would pay is about $4,000 per beneficiary regardless of the price it charges for its product. As a result, if a manufacturer can raise the prices of its products, that increase could offset some or all of the costs associated with the coverage-gap discounts.

Policymakers' decisions about the amount that manufacturers must pay in coverage-gap discounts may have factored into manufacturers' decisions about price increases or launch prices, especially for drugs that have relatively low prices because coverage-gap discounts affect a proportionately larger share of manufacturers' revenues. For drugs and biologics with prices near or above the catastrophic threshold, manufacturer discounts in the coverage gap are small compared with their revenue from Part D prescriptions (Table 5-1, p. 130). For example, based on 2018 data, gross spending (before postsale rebates and discounts) for Revlimid®, a chemotherapy drug used for certain cancers, totaled $4.1 billion. The coverage-gap discount paid by Revlimid's manufacturer totaled about $77 million, or 1.9 percent of gross spending. Because the majority (86 percent) of spending for Revlimid occurred in the catastrophic phase of the benefit (above the OOP threshold), the coverage-gap discount applied to the less than 4 percent of spending that fell in the coverage gap. In comparison, about 75 percent of spending for Lantus Solostar® (a type of insulin) occurred below the OOP threshold. The coverage-gap discount for Lantus Solostar totaled $203 million in 2018, or 8.6 percent of the $2.4 billion in gross spending for this product.

Restructuring Part D to restore incentives to manage spending

In its June 2019 report, the Commission discussed changes to Part D that would simplify the benefit for all enrollees and restore incentives for plans to manage drug spending (Medicare Payment Advisory Commission 2019d). Below the OOP threshold, the new standard benefit would have no coverage gap, making plans responsible for 75 percent of spending between the deductible and the start of the catastrophic phase for all enrollees (Figure 5-4, p. 131). To carry out this change, Part D would eliminate the coverage-gap discount program for enrollees without the LIS and eliminate the coverage gap for LIS enrollees. Above the OOP threshold, consistent with our 2016 recommendations, the policy would provide enrollees with greater financial protection by adding an annual cap on OOP spending. The policy would also phase in a shift of insurance risk from Medicare to plan sponsors and drug manufacturers.

Under the redesigned Part D benefit, Medicare would make larger capitated payments to plan sponsors, with the overall subsidy rate remaining unchanged at 74.5 percent. That is, Medicare's total payments to plans for the basic benefit would remain unchanged if there were

TABLE 5-1

The coverage-gap discount affected a smaller share of spending for higher priced drugs and biologics, 2018

Brand name	Therapeutic class	Total gross spending (in billions)	Coverage-gap discount: Amount (in millions)	Coverage-gap discount: As share of total gross spending	Average gross spending per prescription	Share of gross spending above OOP threshold
Examples of higher priced drugs and biologics						
Revlimid®	Antineoplastic	$4.1	$77	1.9%	$14,217	86%
Harvoni®	Antiviral	1.7	17	1.0	31,673	89
Humira pen®	Analgesics, anti-inflammatory	2.4	57	2.4	6,053	78
Copaxone®	Multiple sclerosis agent	1.2	28	2.3	6,524	83
Examples of other drugs and biologics						
Lantus Solostar®	Diabetic therapy	$2.4	203	8.6%	$530	25%
Eliquis®	Anticoagulant	5.0	541	10.8	549	10
Advair Diskus®	Respiratory therapy agent	2.4	159	6.6	544	16
Lyrica®	CNS agent	3.0	188	6.4	565	28

Note: OOP (out-of-pocket), CNS (central nervous system). "Gross spending" refers to amounts paid at the pharmacy before postsale rebates and discounts.

Source: MedPAC analysis of 2018 Part D prescription drug event data.

no behavioral responses by plan sponsors, manufacturers, or beneficiaries. In practice, because plan sponsors would be liable for a greater share of spending both above and below the OOP threshold, the policy would likely change plan sponsors' formulary incentives and their negotiations with manufacturers over rebates. For example, we anticipate that it would be difficult for manufacturers of high-priced products to offer rebates large enough to make their products financially advantageous for plan sponsors when lower cost products are available. As a result, plan sponsors would likely prefer lower priced products among therapeutic alternatives rather than high-priced, high-rebate products. That change, in turn, would reduce the financial benefit of higher prices for some manufacturers. Collectively, our reforms eliminating the coverage gap and restructuring Part D's catastrophic benefit would involve several policy changes.

Eliminate the coverage gap

The policy to eliminate the coverage gap would discontinue manufacturer discounts below Part D's catastrophic threshold and establish a single defined standard benefit structure for all enrollees.

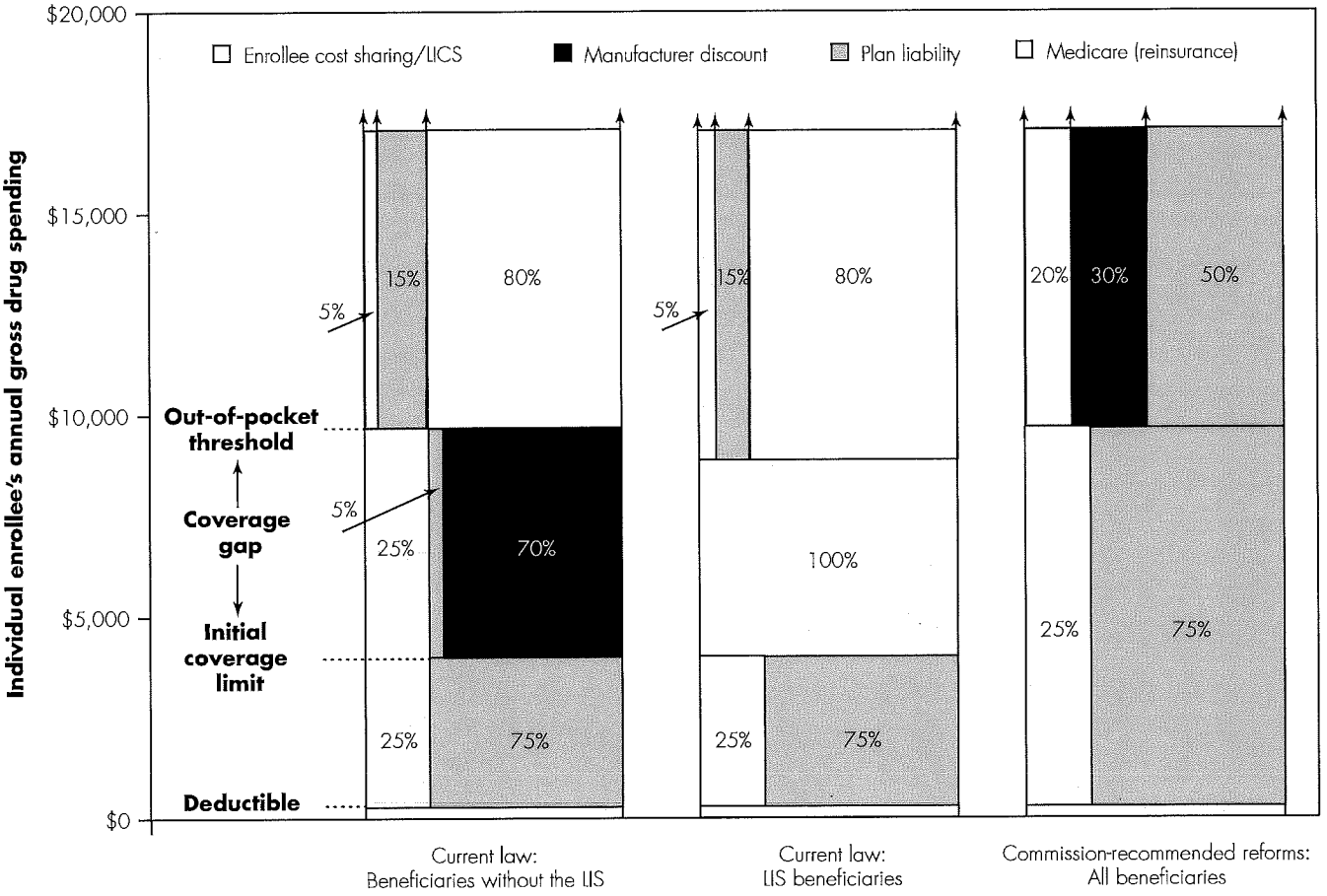
Discontinue brand manufacturer discounts below the catastrophic phase

Discontinuing brand manufacturer discounts below the catastrophic phase would simplify Part D's benefit structure by making plans responsible for a consistent 75 percent of benefits between the deductible and the OOP threshold. Under this change, the price of brand-name drugs would no longer be artificially lowered relative to generics. Plans would have much less incentive to place high-priced, highly rebated drugs on their formularies, while enrollees without the LIS would face stronger incentives to use lower cost products, potentially reducing Part D costs over the longer term.

Absent other changes, removing the coverage-gap discount would increase benefit costs. For example, in 2018, brand discounts totaled nearly $7 billion which, under a restructured benefit, plans would have paid instead of manufacturers. (If the coverage-gap discount rate had been 70 percent in 2018 as it was in 2019 and subsequent years, we estimate that the discount amount would have been over $9 billion.) Under the restructuring of Part D's catastrophic benefit, new manufacturer discounts in

FIGURE 5–4

The Commission's recommended Part D reforms would simplify Part D's benefit structure and give plans stronger incentives to manage drug spending



Note: LICS (low-income cost-sharing subsidy), LIS (low-income subsidy). The coverage gap for enrollees without the LIS (between the initial coverage limit and spending at the out-of-pocket (OOP) threshold) is depicted as it would apply to brond-name drugs. For generic prescriptions filled by enrollees without the LIS, cost sharing in the coverage gap is 25 percent and plans are responsible for 75 percent. For LIS enrollees, Medicare's low-income cost-sharing subsidy pays for all spending in the coverage gap except LIS enrollees' nominal copayments.

Source: MedPAC depiction of Part D's benefit structure under current law and under the Commission's recommended reforms.

the catastrophic phase could replace the coverage-gap discount and thereby offset increased benefit costs.

Plans become responsible for LIS enrollees' coverage-gap spending

By eliminating the coverage gap for LIS beneficiaries, plans would become responsible for 75 percent of LIS enrollees' spending between the deductible and the OOP threshold. Because cost sharing for LIS enrollees is limited to nominal copayments, Medicare's LICS would cover most or all of the 25 percent cost sharing that enrollees without the LIS pay themselves. The policy change would improve plan sponsors' formulary and cost-control incentives. However, because much of what is currently covered by the LICS would become part of the basic benefit design, absent other changes, the new approach would also lead to higher costs for the basic benefit and higher premiums for all Part D enrollees.

TABLE 5-2 **Financial impact of eliminating the coverage gap for LIS enrollees, 2018**

	Financial impact (in billions)
Total low-income cost-sharing subsidy in the coverage gap in 2018	**$13.0**
New plan liability under a consistent benefit structure for enrollees with and without LIS (roughly 75% of the $13 billion)	**$10.0**
Medicare's payments to plans (74.5%)	$7.5
Enrollee premiums (25.5%)	$2.6
Total	$10.0
Effects on Medicare program spending	
Increase in payments to plans for higher benefit costs	$7.5
Increase in payments for low-income premium subsidy	$0.8
Reduction in payments for low-income cost-sharing subsidy	–$10.0
Net effect	**–$1.8**

Note: LIS (low-income subsidy). Components may not sum to totals because of rounding. The low-income cost-sharing subsidy is one component of LIS spending that pays for the difference between the amount of cost sharing charged by a plan and the LIS copayment amount set by law. The other component of LIS spending is the low-income premium subsidy—Medicare payments that cover most or all of the premium (up to a dollar limit that varies by region) on behalf of LIS enrollees.

Source: MedPAC estimate based on Part D prescription drug event data.

To evaluate the effects of this change, we started with an estimate of LIS spending for prescriptions filled in the coverage gap—about $13 billion in 2018.[4] Under a revised benefit structure, the basic Part D benefit would cover 75 percent, or about $10 billion, of LIS enrollees' spending in the coverage gap as currently defined (Table 5-2). Of that $10 billion, Medicare's subsidy payments to plans for all Part D enrollees would increase by about $7.5 billion and the remaining $2.6 billion would be paid in the form of higher enrollee premiums, which would increase by an average of about $4.80 per month. However, other elements of a restructured benefit, such as the manufacturer discount in the catastrophic phase, could offset some of this premium increase. Of the $2.6 billion in enrollee premiums, $0.8 billion would be paid by Medicare for Part D's LIS enrollees, with the remaining $1.8 billion borne by Part D enrollees without the LIS. Assuming no behavioral changes, the financial impact for Medicare in this example would be the net effect of higher payments to plans for the basic Part D benefit ($7.5 billion) and higher LIS spending on premiums ($0.8 billion), offset by $10 billion in lower LICS spending. Combined, there would be a net reduction in Medicare program spending of $1.8 billion.

Restructure Part D's catastrophic benefit

The Commission's recommendations to restructure the catastrophic benefit would eliminate beneficiary cost sharing in the catastrophic phase (thereby creating an annual cap on OOP costs) and lower Medicare's reinsurance in favor of manufacturer discounts and greater plan liability.

Eliminate beneficiary cost sharing in the catastrophic phase

In 2018, 3.9 million, or 8.3 percent, of Part D enrollees reached Part D's OOP threshold. Among those individuals, 2.7 million (70 percent) received the LIS and 1.1 million did not (Table 5-3). LIS enrollees are much more likely than other enrollees to reach the catastrophic phase of the benefit (19 percent vs. 3 percent, data not shown), reflecting their higher average drug spending. Individuals who have high spending and do not receive the LIS pay 5 percent coinsurance on prescriptions in the catastrophic phase with no limit on annual OOP costs.[5] In 2018, spending on the 5 percent coinsurance for those enrollees amounted to $1.3 billion. LIS enrollees who have high spending are also subject to 5 percent coinsurance in the

TABLE 5-3 **Part D enrollees reaching the benefit's catastrophic phase, 2015–2018**

	2015	2016	2017	2018	AAGR, 2015–2018
Number of enrollees reaching OOP threshold (in millions)					
LIS enrollees	2.6	2.6	2.6	2.7	1.3%
Enrollees without LIS	1.0	1.1	1.0	1.1	3.3%
All	3.6	3.6	3.6	3.9	1.9%
Share of all Part D enrollees	8.7%	8.3%	8.0%	8.3%	N/A
Cost-sharing liability in the catastrophic phase (in billions)					
LIS enrollees	$1.7	$1.8	$1.9	$2.1	1.3%
Enrollees without LIS	0.9	1.0	1.1	1.3	12.7%
Total	2.6	2.8	3.0	3.4	9.9%

Note: AAGR (average annual growth rate), OOP (out-of-pocket), LIS (low-income subsidy), N/A (not applicable). Components may not sum to totals due to rounding.

Source: MedPAC analysis of Part D prescription drug event data.

catastrophic phase, but their cost-sharing obligation is fully covered by Medicare's LICS. For LIS enrollees, in 2018, Medicare's LICS paid about $2.1 billion for coinsurance in the catastrophic phase.

Under a restructured Part D benefit, beneficiaries would have no cost-sharing liability in the catastrophic phase, providing complete financial protection to enrollees once they reached the OOP threshold (consistent with our 2016 recommendation). This protection would be particularly valuable for beneficiaries with the highest spending who do not receive the LIS. For example, in 2018, of the 1.1 million high-spending enrollees without the LIS, about 110,000 paid $2,800 or more in cost sharing for prescriptions filled in the catastrophic phase of the benefit.

Under current law, in 2020, the catastrophic phase starts when an enrollee accrues $6,350 in OOP costs, but brand manufacturer discounts in the coverage gap count toward that amount. A beneficiary who takes the average mix of generic and brand-name drugs would reach that threshold by spending about $2,750 of their own money and would receive $3,600 in manufacturer discounts. Beneficiaries who use a higher than average share of generic drugs would need to spend more of their own money to reach the OOP threshold. If the coverage-gap discount were eliminated in 2020, beneficiaries without the LIS, regardless of their mix of brand-name and generic drugs, would have to pay the full $6,350 to reach the OOP threshold. For this reason, policymakers could consider a lower catastrophic threshold under a restructured benefit to ensure that beneficiary OOP spending does not exceed the level it would have been had the coverage-gap discount remained.

Eliminating cost sharing in the catastrophic phase would result in higher benefit costs. For example, in 2018, the $3.4 billion in cost sharing that was paid by enrollees without the LIS and by Medicare's LICS for LIS enrollees would instead have been included in plan bids. In turn, premiums for all Part D enrollees would have increased by roughly $1.60 per month. Medicare's spending to subsidize the basic Part D benefit for all enrollees would increase by $2.5 billion (74.5 percent of $3.4 billion). In the aggregate, premiums would increase by $0.9 billion, with about $0.3 billion of that amount covered by Medicare's premium assistance for LIS enrollees. In addition, the policy would likely increase prescriptions filled in the catastrophic phase of the benefit by beneficiaries without the LIS. As a result, effects on Medicare's subsidy payments for Part D's basic benefit costs and enrollee premiums would likely be higher than

the static estimate that assumes no behavioral response. Policymakers could require manufacturers of brand-name drugs to provide a somewhat higher discount in the catastrophic phase to pay for the new financial protections provided to high-cost enrollees. The net effect on Medicare program spending would be an increase of $0.7 billion ($2.5 billion in higher spending on the basic benefit and $0.3 billion in higher LIS spending on premiums, minus $2.1 billion in lower LICS spending).

Establish a manufacturer discount in the catastrophic phase

In its June 2019 report, the Commission discussed converting the coverage-gap discount to a discount in Part D's catastrophic phase as a way to provide plan sponsors and manufacturers with better formulary and pricing incentives (Medicare Payment Advisory Commission 2019d). In the recommendation described here, the manufacturer discount would apply to prescriptions in the catastrophic phase for both brand-name drugs and biologics (including biosimilars) and generic prescriptions to reach CMS's threshold to be placed on a specialty tier (with an average price of $670 per month or more in 2020). The manufacturer discount would apply to prescriptions filled in the catastrophic phase by LIS beneficiaries as well as beneficiaries without the LIS.

Compared with the current discount in the coverage gap, a manufacturers' discount in the catastrophic phase would apply more directly to drugs and biologics that command high prices, potentially acting as a drag on price growth. Because the dollar amount of the discount would increase proportionately with the price of the drug, high-priced products would be subject to a larger financial liability than lower priced products. Compared with a manufacturer discount in the coverage-gap phase, some analysts believe that a discount in the catastrophic phase could make the prospect of raising prices less attractive for manufacturers. Others believe that manufacturers would launch new drugs at prices high enough to compensate for the discount liability. The extent to which manufacturers could increase prices or launch new drugs at higher prices would vary by product and would depend on multiple factors, including the degree of competition within a therapeutic class and Medicare's market share of that product. Policymakers could structure the discount so that if average prices of drugs subject to the discount increased faster than a benchmark (such as average Part D spending), the discount rate would increase commensurately.

In 2018, if the coverage-gap discount rate had been 70 percent (as was the case in 2019 and subsequent years), manufacturer discounts would have totaled about $9 billion. Based on the distribution of claims in 2018, we estimate that Part D would need a manufacturer discount rate in the catastrophic phase of about 15 percent—applied to prescriptions filled by beneficiaries both with and without the LIS—to ensure that the aggregate amount paid by manufacturers would be as large as the amount that would be paid under the current coverage-gap discount program. That estimate is for one year (2018) and does not incorporate any behavioral assumptions about how beneficiaries, plan sponsors, and manufacturers might respond to a discount in the catastrophic phase. The estimate also does not reflect any changes in the distribution of Part D spending in later years as new products entered the market.

Alternatively, a discount in the catastrophic phase could be set at a higher rate to offset other costs of the restructured benefit. Policymakers could also choose to pay for the restructured benefit through higher enrollee premiums, higher Medicare program spending, or both. For example, we estimate that in 2018, a 20 percent discount rate would have been needed to replace the coverage-gap discount and cover the costs of a new OOP cap. An estimated 35 percent rate would have been needed to cover both of those policy changes as well as the costs of eliminating the coverage gap for LIS enrollees. However, it is worth emphasizing that those figures are based on a snapshot of 2018 spending. In future years, as more high-priced drugs enter the market, the share of Part D spending made up of catastrophic benefits is likely to grow. In turn, a discount in the catastrophic phase would cover a larger share of Part D spending, offsetting more of the costs of the expanded benefits. Reflected in the recommendations presented later in this chapter, the Commission chose a manufacturer discount rate of at least 30 percent to include manufacturers among the stakeholders that would bear strong direct effects of drug price increases. A 30 percent discount would also help offset what would otherwise be increases in enrollee premiums and Medicare program spending resulting from Part D's new benefit structure.

Lower Medicare's individual reinsurance and increase plan liability

Part D's individual reinsurance is one component of a system of risk-sharing mechanisms. Before the start of Part D, stand-alone PDPs did not exist. Policymakers initially included Medicare's reinsurance and risk corridors

to encourage plan sponsors to enter this new market and compete. In 2015, the Commission reviewed Part D's tools for sharing risk—reinsurance, risk adjustment, and risk corridors—and discussed whether all three were still necessary in what had by then become an established market (Medicare Payment Advisory Commission 2015).

Reinsurance is one mechanism to give plan sponsors protection against unpredictable variation in pharmacy spending. For commercial and employer health plans, private individual reinsurance (also called individual stop-loss protection) is designed to serve a very specific purpose: to offset the unpredictable financial risk of extremely high claims from a few members. Because most commercial health plans insure both medical and pharmacy benefits, reinsurance contracts written for those plans generally cover both types of spending.

The more generous structure of Medicare's reinsurance and the predictability of most spending covered by Part D reinsurance suggest that individual reinsurance is serving a different function than it does for commercial health plans (Medicare Payment Advisory Commission 2016). In commercial plans, reinsurance typically has a higher spending threshold and may cover only the top 1 percent or 2 percent of enrollees with the highest spending (Bachler et al. 2019, Medicare Payment Advisory Commission 2015). By comparison, Medicare pays reinsurance for about 8 percent of Part D enrollees. Private reinsurers of commercial plans may exclude individuals with predictably high spending from future reinsurance coverage. Rather than acting as a stop loss against unexpectedly high spending, Medicare's reinsurance has been providing targeted cost-based reimbursement for high-cost enrollees, whether spending for those individuals is predictable or not.

The Commission's new approach to restructuring Part D would lower Medicare's reinsurance from 80 percent to 20 percent of catastrophic spending and increase plan sponsors' financial risk for benefit spending. More of Medicare's overall subsidy would be paid through capitated payments, adjusted by risk scores that would be recalibrated to the higher level of plan liability. Those measures would give plan sponsors stronger incentives to manage benefits, which could improve their formulary design decisions. Medicare's overall subsidy would remain unchanged at about 74.5 percent of basic benefits, and the share of basic benefit costs paid by enrollees would remain at about 25.5 percent. Because of the sizable nature of this shift in risk, policymakers could temporarily tighten Part D's risk corridors to protect plan sponsors and beneficiaries from unintended consequences. The Commission anticipates phasing in its recommendations over several years to give plan sponsors time to adjust to the new benefit structure. After the phase-in period, the Commission could revisit the issue of whether risk corridors are still needed.

A restructured Part D benefit

Table 5-4 (p. 136) compares a recommended restructured Part D benefit with the current defined standard benefit. The restructured benefit would eliminate the coverage-gap discount program that currently applies to enrollees without the LIS as well as the coverage gap for LIS enrollees. Those changes would create a standard benefit structure for all enrollees, and plans would become responsible for 75 percent of benefits between the deductible and the OOP threshold. The restructured benefit would have no beneficiary cost sharing in the catastrophic phase. Medicare's individual reinsurance would be lowered to 20 percent, with plan sponsors responsible for 80 percent of low-priced generics (below the specialty-tier dollar threshold) and 50 percent for all other drugs and biologics. The effects on stakeholders of restructuring Part D in this way would vary depending on the specific parameters chosen. Below, we highlight some key tradeoffs in setting those parameters and considerations for two types of Part D plans: those that serve LIS enrollees and employer group waiver plans.

Tradeoffs between a lower OOP threshold and benefit and premium costs

In 2022, Part D's OOP threshold is projected to be about $7,100. Under that threshold, enrollees without the LIS who reach the threshold and take an average mix of brand-name and generic prescriptions would pay about $3,100 themselves and brand manufacturers would provide about $4,000 in coverage-gap discounts. If the coverage-gap discount program were eliminated, most individuals who now reach the catastrophic phase would not likely reach it as quickly, and some would not reach it at all.

Setting the OOP threshold at $3,100 in 2022 would ensure that most enrollees reach the catastrophic phase with about the same amount of cost-sharing liability as under current law. If policymakers set the OOP threshold at a lower amount, it would provide greater financial protection for all enrollees. More beneficiaries would reach the

TABLE 5–4 The parameters of a restructured Part D benefit

	Current benefit	Restructured benefit
Transition period to the new catastrophic benefit	N/A	4 years
Benefit phases below OOP threshold:		
Enrollee cost sharing between deductible and ICL	25%	25%
Plan liability between deductible and ICL	75%	75%
Coverage gap between ICL and catastrophic phase?	Yes	No
Brand manufacturer discount	70% in coverage gap (prescriptions filled by enrollees without LIS)	None
Projected OOP threshold in 2022	$3,100 ($7,100)*	$3,100
Total spending at OOP threshold	About $11,000	About $11,000
Distribution of catastrophic spending (above the OOP threshold):		
Beneficiary cost sharing	5%	0%
Medicare reinsurance	80%	20%
Plan liability	15%	80% for lower priced generics 50% for brands and high-priced generics
Manufacturer discount**	0%	30% for certain prescriptions filled by enrollees with and without LIS

Note: N/A (not applicable), OOP (out-of-pocket), ICL (initial coverage limit), LIS (low-income subsidy).
*Under current law, in the coverage gap, both beneficiary spending and the 70 percent discount provided by brand manufacturers count toward the OOP threshold. In 2022, at the average mix of brand and generic spending, about $3,100 of the $7,100 threshold, would be paid by the beneficiary and $4,000 would be covered by manufacturer discounts.
**Would apply to brand-name drugs, biologics, biosimilars, and certain high-priced generic drugs.

Source: Illustrative parameters for MedPAC-recommended changes to Medicare's Part D benefit structure, 2020.

catastrophic phase of the benefit than under current law. However, because there would be no cost sharing in the catastrophic phase, Part D enrollees who reach the lower OOP threshold would likely use more medications relative to a higher OOP threshold, potentially increasing polypharmacy issues among some beneficiaries. That change, in turn, would tend to put upward pressure on Part D benefit costs and enrollee premiums.

Trade-offs of a higher manufacturer discount in the catastrophic phase

Striking the right balance between plan and manufacturer liability will be crucial in providing better plan incentives while restraining high price growth. In the restructured benefit shown in Table 5-4, the catastrophic benefit would consist of lower Medicare reinsurance (20 percent), a new manufacturer discount (30 percent), and plan liability (50 percent for brand-name drugs, high-priced generics, and biologics and 80 percent for lower priced generic drugs). Increasing plan liability from the current 15 percent to a higher percentage is important in providing plan sponsors with stronger incentive to manage spending.

If policymakers were to select a manufacturer discount lower than 30 percent, plans would bear more insurance risk, which would provide them with stronger incentives to manage spending. Plans might also negotiate harder

for rebates but would still have limited ability to negotiate rebates for unique therapies. However, benefit costs and enrollee premiums would both be higher.

The Commission chose to recommend a manufacturer discount of at least 30 percent to discourage price increases and to help offset increases in benefit costs and enrollee premiums. Because the new manufacturer discount would apply more directly to high-priced products, it could be particularly useful for therapies in drug classes that have few or no competitors. Under a reform in which the discount rate in the catastrophic phase would increase proportionately with the average growth in catastrophic spending, manufacturers could be deterred from raising prices. However, the effectiveness of the discount at restraining price growth would vary across manufacturers and would depend on Medicare's share of each product's market. In addition, if a higher manufacturer discount further reduced plan sponsors' liability, on the margin, that could weaken plan incentives to manage spending. For that reason, if the discount were structured to increase beyond 30 percent commensurately with growth in average catastrophic prices, policymakers could consider reducing the share of catastrophic benefits paid through Medicare's reinsurance rather than reducing plans' share.

Considerations for plans serving low-income beneficiaries

In 2017, LIS enrollees made up 71 percent of beneficiaries with spending high enough to reach Part D's catastrophic phase. Most LIS beneficiaries are in plans that serve large numbers of LIS enrollees, including basic stand-alone PDPs and a type of specialized MA plan known as a dual-eligible special needs plan (D–SNP). The Commission's recommended Part D reforms would require plans to bear more financial risk by expanding the use of capitated payments and reducing the use of cost-based payments for the LICS and reinsurance. To ensure stability in plan options for LIS beneficiaries, policymakers would need to phase in the new structure of Medicare's subsidies over several years. New tools would help plan sponsors better manage drug spending for LIS enrollees, and CMS would need to recalibrate the Part D risk adjustment system to reflect the higher plan liability.

A significant number of Part D plans serve primarily LIS enrollees LIS enrollment varies across plans, largely due to deliberate policy choices in both the Part D and MA programs. Medicare encourages LIS beneficiaries to enroll in basic PDPs by setting the maximum amount the program will pay for low-income premium subsidies at regional benchmarks calculated from plans' premiums for basic coverage. In 2019, of the 7.3 million LIS beneficiaries enrolled in stand-alone PDPs, more than 90 percent were in plans that offered basic coverage. In that year, LIS beneficiaries accounted for 55 percent of enrollees in basic PDPs. Of the LIS beneficiaries in PDPs, 95 percent were enrolled in PDPs offered by five large companies—CVS Health, UnitedHealth Group, Humana, WellCare (recently purchased by Centene), and Cigna (including its subsidiary Express Scripts).

Of the 5 million LIS beneficiaries enrolled in MA–PDs in 2019, just over half (2.5 million people) were in traditional plans and another 45 percent (2.2 million people) were in D–SNPs.[6] Traditional MA–PDs are open to all beneficiaries in a plan's service area, but special needs plans are limited to certain types of beneficiaries, with D–SNPs serving dual eligibles. As a result, LIS beneficiaries account for a relatively small share of enrollment in traditional MA–PDs (18 percent) but account for virtually all D–SNP enrollment.[7] LIS enrollment in MA–PDs is less concentrated among a few major companies than is LIS enrollment in PDPs. In addition to large, vertically integrated health plans, MA plan sponsors include a broader variety of companies such as smaller regional organizations, religious-affiliated groups, and integrated delivery systems. However, most sponsors of smaller MA–PDs contract with large pharmacy benefit managers (PBMs) to provide outpatient drug benefits and negotiate postsale rebates and discounts with drug manufacturers and pharmacies.[8]

In 2019, there were 1,021 Part D plans in which LIS beneficiaries made up the majority of each plan's enrollees (Table 5-5, p. 138). (Those majority-LIS plans made up about one-quarter of all Part D plans in 2019 (data not shown).) Those plans covered about two-thirds of the LIS population (8.2 million out of 12.7 million), with most individuals enrolled in basic PDPs and D–SNPs.

Monitor effects of restructuring on MA–PDs that serve mostly LIS enrollees The reforms would result in higher capitated payments (consisting of Medicare's direct subsidy payments to plans and premiums paid by enrollees and by Medicare for LIS enrollees) for all enrollees, but the impact for LIS beneficiaries would be larger. Table 5-6 (p. 139) shows how 2017 spending was financed for beneficiaries with and without the LIS and demonstrates how the role of each funding stream would change under the Commission's recommended reforms.

TABLE 5-5 **A significant number of Part D plans served primarily LIS beneficiaries, 2019**

		Enrollees (in thousands)		Average share of enrollees	
	Plans	With LIS	Without LIS	With LIS	Without LIS
Plans with majority-LIS enrollment					
Basic PDPs	187	5,124	2,387	68%	32%
Traditional MA–PDs	150	334	80	81	19
C–SNPs	14	49	4	92	8
D–SNPs	413	2,238	8	100	<1
I–SNPs	81	78	4	95	5
MMPs	50	380	1	100	<1
PACE	126	43	1	99	1
Total	1,021	8,246	2,485	77	23

Note: LIS (low-income subsidy), PDP (prescription drug plan), MA–PD (Medicare Advantage–Prescription Drug [plan]), C–SNP (chronic condition special needs plan), D–SNP (dual-eligible special needs plan), I–SNP (institutional special needs plan), MMP (Medicare–Medicaid Plan), PACE (Program of All-Inclusive Care for the Elderly). Figures based on Part D enrollment data for April 2019. Does not include plans in the U.S. territories.

Source: MedPAC analysis of CMS Part D enrollment data.

Under this reform package, Medicare's capitated payments to plans would account for a substantially larger share of total spending, rising from 28 percent to 58 percent for LIS beneficiaries and from 40 percent to 60 percent for the other Part D beneficiaries. The share of spending financed by Medicare's reinsurance and the LIS would decline, but it is worth noting that they and the other types of funding would still account for about 40 percent of total spending.

In dollar terms, the recommended reforms would lead to higher capitated payments for both kinds of beneficiaries, but the increase for LIS beneficiaries would be larger. The average monthly capitated payment for LIS beneficiaries would more than double, rising from $139 to $289, while the average payment for Part D beneficiaries without the LIS would rise from $87 to $130. The increase for LIS beneficiaries, $150, would be larger because these beneficiaries have higher gross spending, on average, than Part D beneficiaries without the LIS and because the majority of that spending is currently financed through Medicare's reinsurance and the LICS (40 percent and 31 percent, respectively). In contrast, Medicare's reinsurance payments for beneficiaries without the LIS account for 23 percent of gross drug spending. Under the recommended reform package, Medicare's payments for reinsurance and the LICS would be lower but would be mostly offset by higher capitated payments. As a result, capitated payments for LIS beneficiaries would be an average of 2.2 times higher than capitated payments for Part D beneficiaries without the LIS (compared with 1.6 times higher under the current program).

Because of the differences between LIS and the other Part D beneficiaries, we interviewed several plan sponsors and actuaries with Part D plan expertise to learn about their experience with the LIS population. These sponsors consisted of a mix of large, for-profit companies that operate both stand-alone PDPs and MA–PDs and smaller, nonprofit companies that operate regional MA–PDs. Each sponsor had at least one plan, such as a basic PDP or D–SNP, in which most of the enrollees were LIS beneficiaries. Although interviewees were not drawn from a representative sample of all majority-LIS plans, their comments helped to highlight issues that policymakers could consider related to restructuring Part D.

There was broad agreement among interviewees that Part D reforms should be phased in to give plans time to adjust to the added financial risk and to avoid unnecessary disruptions. All interviewees emphasized

TABLE 5–6

An illustrative example of how the Commission's recommended reforms would affect spending for LIS enrollees versus other Part D enrollees

	Average gross spending (per enrollee per month, 2017)			Distribution of gross spending	
	Actual	Under reformed benefit	Change	Actual	Under reformed benefit
LIS enrollees					
Total gross drug spending	$502	$502	$0	100%	100%
Medicare reinsurance	202	50	–152	40	10
Capitated payments	139	289	150	28	58
LICS	155	81	–74	31	16
Manufacturer discounts in catastrophic phase	0	75	75	0	15
Out-of-pocket spending	6	6	0	1	1
Other Part D enrollees					
Total gross drug spending	$218	$218	$0	100%	100
Medicare reinsurance	49	12	–37	23	6
Capitated payments	87	130	43	40	60
Manufacturer coverage-gap discounts	16	0	–16	7	0
Manufacturer discounts in catastrophic phase	0	18	18	0	8
Out-of-pocket spending	44	36	–8	20	17
Other	21	21	0	10	10
Ratio of LIS capitated payments to other Part D beneficiaries' capitated payments	1.6	2.2			

Note: LIS (low-income subsidy), LICS (low-income cost-sharing subsidy). "Other Part D enrollees" refers to Part D enrollees without the LIS. "Gross spending" refers to amounts paid at the pharmacy before postsale rebates and discounts. The "under reformed benefit" columns show the combined effects of the following Part D reforms: eliminating the coverage gap for LIS enrollees, eliminating the coverage-gap discount program, adding an annual cap on beneficiary out-of-pocket costs, lowering the use of reinsurance in the catastrophic phase from 80 percent to 20 percent, requiring manufacturers of brand-name drugs to provide a discount of 30 percent on brand-name drugs and high-cost generic drugs used in the catastrophic phase, and increasing the share of catastrophic benefits financed by capitation payments from 15 percent to 50 percent for brands and generics and 80 percent for all other drugs. Capitated payments consist of Medicare's direct subsidy payments to plans and premiums paid by enrollees and LIS for LIS enrollees. The "other" figures include payments by patient assistance organizations and third-party payers other than Part D plans that reduce beneficiary cost-sharing liability. Figures do not incorporate behavioral responses by plans and beneficiaries that would change total gross drug spending. Figures do not reflect the effects of postsale rebates and discounts and thus cannot be used to estimate the effect that the proposed reforms would have on Part D premiums. Components may not sum to totals because of rounding.

Source: MedPAC analysis based on average monthly spending amounts per enrollee with and without the LIS in 2017 Part D prescription drug event data.

that the Part D risk adjustment model would need to be recalibrated to ensure that payments for LIS beneficiaries remained adequate.

Interviewees distinguished between the new liability that plans would bear for what is now coverage-gap spending compared with higher plan liability in Part D's catastrophic phase. Our interviewees did not believe that requiring plans to cover 75 percent of costs in the coverage gap would pose the same risk as the catastrophic benefit costs because coverage-gap spending falls within a narrow range and is relatively predictable. However, interviewees expressed concern that payment rates for some high-cost beneficiaries might be too low. The primary concern was that even with higher capitated payments, reductions in Medicare's reinsurance could lead to an increase in "high-cost outlier" cases in which risk-adjusted payments were substantially below actual costs. One interviewee said that Medicare should continue to use reinsurance to cover at

least some spending in the catastrophic phase because that would take some pressure off the risk adjustment system (i.e., CMS's risk adjustment model would not need to predict spending for high-cost beneficiaries as accurately as it otherwise would).

Interviewees said that smaller plans, such as regional MA–PDs, would be more vulnerable to high-cost outliers, but when asked, they did not provide specifics on how a "smaller plan" might be defined. They noted that some plan sponsors might respond by purchasing private reinsurance to limit their potential exposure—although one sponsor said the profit markups on this coverage would make it prohibitively expensive—and said that policymakers could provide additional protection while the reforms were being implemented by modifying Part D's risk corridors.

We also examined data on Part D's risk corridor payments for 2015, the most recent available, to compare the performance of plans in which LIS beneficiaries made up the majority of enrollees with the performance of other plans. The risk-corridor data show how the actual costs that plans incurred to provide Part D benefits compared with the assumptions plans used in their bids. We found that bids for majority-LIS plans were about as accurate as bids for other plans, indicating that majority-LIS plans could accurately predict the costs for their enrollees and were not at greater risk of unexpected financial losses. In addition, majority-LIS plans typically did a better job of predicting how much of their enrollees' drug spending would be covered by the LICS. Because the recommended reforms would take some spending that Medicare's LICS now covers and make it part of the basic Part D benefit, these findings suggest that majority-LIS plans would be able to accurately account for the effects of those changes when they developed their bids.

Considerations for employer group waiver plans

Employer group waiver plans (EGWPs) are sponsored by employers that contract directly with CMS or on a group basis with an insurer or PBM to administer the Part D benefit. They differ from employer plans that receive Part D's retiree drug subsidy (RDS) in that Medicare is the primary payer rather than the employer.[9] Under accounting standards, private employers and state and local governments are required to calculate and report their unfunded liabilities for future pensions and other postemployment retirement benefits such as for prescription drugs. By putting retirees into EGWPs that benefit from both Medicare's general Part D subsidy as well as manufacturer discounts in the coverage gap, employers substantially reduce the magnitude of their unfunded liability.

EGWPs have distinct characteristics from other Part D plans. As a result, certain pieces of the recommended Part D reforms are likely to have a different impact on EGWPs than on other plans. One key difference is that EGWPs do not submit bids. Instead, Medicare pays EGWPs based on the national average of bids from nonemployer Part D plans. Another difference is that EGWPs are not eligible for risk-corridor payments. Under the restructured benefit, plan bids would increase to reflect their higher liability for benefit costs in the coverage gap and the catastrophic phase. In turn, Medicare's direct subsidy payments to EGWPs would also increase.

EGWPs receive a disproportionate share of coverage-gap discounts: In 2018, EGWPs had 16 percent of Part D enrollees but received 45 percent of coverage-gap discounts (Medicare Payment Advisory Commission 2020b). EGWPs received more discounts because they tend to offer more generous benefits that supplement the standard Part D benefit. Under Part D's "true out-of-pocket" provision, those supplemental benefits do not count as an enrollee's OOP costs. As a result, EGWP enrollees who reach the coverage gap tend to stay there longer than enrollees without supplemental coverage. EGWPs also receive more discounts because they have very few LIS enrollees and thus a higher share of enrollees eligible for the discounts. In 2018, 98 percent of enrollees in EGWPs were eligible for coverage-gap discounts because they did not receive the LIS, compared with the roughly two-thirds of enrollees in other Part D plans. As a result, eliminating the coverage-gap discount under the reform would likely have a larger financial impact on EGWPs than on other Part D plans.

Under the reformed benefit, there would be a new manufacturer discount in the catastrophic phase that would apply to all enrollees. However, if EGWPs continued to provide supplemental benefits that prevented or delayed enrollees from reaching the catastrophic phase of the benefit, EGWPs would receive fewer manufacturer discounts than they do now. At the same time, because CMS would need to go through the rule-making process to implement the restructured benefit, we expect employers would have time to adjust their benefit offerings or switch to providing the prescription drug benefit through an RDS-eligible plan before facing the full financial impact of the reform.

Other modifications to Part D associated with a restructured benefit

The Commission believes that a Part D reform package that requires plan sponsors to assume greater financial risk should include complementary reforms to provide plan sponsors with greater flexibility to manage drug spending. In its June 2016 recommendations, the Commission included modifying the LIS to encourage greater use of lower cost drugs, removing protected status from two of the six drug classes for which plan sponsors must now cover all drugs on their formularies, streamlining the process for formulary changes, requiring prescribers to provide supporting justifications with more clinical rigor when applying for exceptions, and permitting plan sponsors to use selected tools to manage specialty-drug costs.[10] Part D's risk adjustment system would be recalibrated, and risk corridors could be modified as well.

Part D plan sponsors use formulary tools to manage benefits, but are subject to more constraints than commercial plans

The universe of drugs that Part D plans can cover generally includes, with a limited number of exceptions, any outpatient prescription agent approved by the Food and Drug Administration whose manufacturer has signed a contract with CMS to provide statutory rebates in the Medicaid program.[11] From that range of products, the pharmacy and therapeutics committee of each Part D plan sponsor selects specific drugs and biologics to include on its formulary. Those selections are based on considerations about therapeutic effectiveness as well as the relative price of competing products, net of any rebates and discounts negotiated with manufacturers and pharmacies. To make sure that each plan's formulary design does not substantially discourage enrollment by certain eligible individuals, CMS reviews plan formularies to check that they include medicines in a wide range of therapeutic classes used by the Medicare population. For most drug classes, plans must cover at least two chemically distinct drugs, as well as "all or substantially all drugs" in six protected classes—anticonvulsants, antidepressants, antipsychotics, immunosuppressants, antiretrovirals, and antineoplastics.

Sponsors manage the Part D benefit using the same strategies they employ for commercial clients: designing tiered formularies with differential cost sharing to encourage use of lower cost drugs, which gives sponsors leverage in negotiations with drug manufacturers for rebates. Plan sponsors may use utilization management tools such as prior authorization and step therapy to encourage enrollees to use generics and preferred drugs or to help ensure patient safety. In general, plan sponsors would have the greatest leverage for price concessions when they can credibly threaten not to cover a drug on their formularies. However, sponsors are subject to more regulatory oversight in Part D than in the commercial sector, and CMS must approve each plan's formulary and utilization management requirements. Some Part D regulations, such as the protected-class policy, expand beneficiaries' access to drug therapies but can also reduce plan sponsors' negotiating leverage with manufacturers. The policy likely contributes to the high prices of some drugs in the protected classes (Centers for Medicare & Medicaid Services 2018b, Kocot et al. 2019).

Medicare also requires plan sponsors to establish a process for coverage determination and appeals. There are limits as to what available data can tell us about how well Part D's exceptions and appeals processes work. Nevertheless, CMS data show that in 2017, 3.5 percent of Part D transactions were rejected at the pharmacy because the drug was not on the plan's formulary or because of plan requirements for prior authorization, quantity limits, or step therapy (Office of Inspector General 2019). Of those reported rejections, about 10 percent proceeded to a plan coverage determination, and more than 70 percent of those claims were ultimately approved in favor of the patient by either the plan itself or by an independent review entity.

A more constructive approach toward ensuring appropriate access would be to provide enrollees and prescribers with real-time information about formulary coverage and utilization management requirements. (See text box on resolving coverage issues at the point of prescribing, p. 142.) These tools could reduce the need for appeals and increase the likelihood that beneficiaries receive an appropriate medicine in a timely manner. If built into the prescriber's workflow, standardized approaches to real-time benefit check, electronic prior authorization, and automated coverage determinations could also save patients and providers significant time and resources and speed up delivery of care (American Medical Association–convened workgroup of 17 state and specialty medical societies 2019).

Part D's low-income cost-sharing subsidy limits out-of-pocket costs, but also reduces incentives to use lower cost drugs

The cost-sharing subsidy sharply reduces OOP costs for LIS beneficiaries. Medicare pays for the deductible and

Resolving coverage issues at the point of prescribing

Rather than relying on the exceptions and appeals process, a better approach to resolving questions about coverage would be to use electronic tools such as real-time benefit tools (RTBTs) and electronic prior authorization (ePA).

For several years, health plans and pharmacy benefit managers (PBMs) have operated portals that prescribers could use to look up formulary and benefit (F&B) information. However, portals can be time consuming because they fall outside the regular workflow of prescribers, and providers typically need to navigate several portals for information across their patient panel. Part D plan sponsors currently are required to disseminate F&B information on a nightly, weekly, or monthly schedule, but that approach does not provide patient-specific data. Even when available, physicians may ignore F&B information because they have experienced inaccuracies or because it is displayed in a confusing manner. Physicians in one recent roundtable said they would like to know the approximate cost-sharing amount their patients would pay for various medicines rather than just formulary status and cost-sharing tier (BenMedica 2019). In addition, beneficiaries would also like to know the drug's cash price (to decide whether to use their plan benefit) as well as the availability of cost-sharing assistance (CoverMyMeds 2020).

By comparison, RTBTs operate as a module within a patient's electronic health record (EHR). RTBT technology allows the prescriber to see patient-specific details about benefits—such as whether a drug is covered on a formulary, alternative drugs that are covered, prior authorization requirements, total drug cost, beneficiary cost sharing, and pharmacy network status—before ordering a prescription. ePA tools allow the prescriber to submit a request to the patient's plan in real time and, for automated plan reviews, potentially receive approval much more quickly than manual plan reviews. After receiving an ePA approval, the prescriber orders the prescription and sends it to the desired pharmacy for dispensing.

Part D plan sponsors have long been required to support electronic prescribing, which in 2018 was used by approximately 73 percent of prescribers and 99 percent of pharmacies (SureScripts 2018). In 2019, CMS finalized a rule (CMS–4180–F) requiring Part D sponsors to implement one or more RTBTs capable of integrating with at least one prescriber's EHR system by January 1, 2021. However, the extent to which this requirement increases the use of RTBTs in Part D will depend on the degree to which clinicians—who face no requirements under this rule—adopt them when prescribing for their Medicare patients.

Although many EHR vendors, payers, and PBMs already support RTBTs and ePA, phone and fax continue to be the most common ways of completing prior authorization (American Medical Association 2019, CoverMyMeds 2020). One key reason is that the electronic tools do not communicate with all relevant PBMs. For example, SureScripts, which is partly owned by CVS Health and Express Scripts, does not include RTBT data from OptumRx, which is owned by UnitedHealthcare, while OptumRx's tool does not support CVS Health or Express Scripts (Galewitz 2019). There are no industry-wide electronic standards for using the electronic tools, and certain proprietary features of EHRs prevent systems from communicating with one another.

Perhaps the most essential requirement for adoption of electronic tools is clinician acceptance and use, which can require paying fees to vendors and embracing practice pattern change. Some prescribers may not be aware of the tools. According to one recent survey, only 21 percent of physicians reported that they knew their EHR system offered ePA (American Medical Association 2019). In addition, some prescribers require demonstration that the tools could lead to efficiencies rather than contribute to greater workload. ■

coverage gap for most LIS enrollees, and Part D law also sets maximum amounts that LIS beneficiaries pay for each prescription, which cannot be modified by CMS or plan sponsors. In 2017, LIS enrollees paid, on average, $6 per month out of pocket, or about 1 percent of their average gross drug spending of $502 per month. By comparison, all other enrollees paid an average of $44 per month out of pocket, or about 20 percent of their average gross

TABLE 5-7 **LIS beneficiaries have weaker incentives to use lower cost drugs**

Formulary tier	Drug category	Cost sharing in 2020: Median for stand-alone Part D plans	Cost sharing in 2020: Maximum for LIS beneficiaries
Tier 1	Preferred generic drugs	$0 copayment	$3.60 copayment or less for most beneficiaries
Tier 2	Other generic drugs	$3 copayment	
Tier 3	Preferred brand-name drugs	$42 copayment	$8.95 copayment or less for most beneficiaries
Tier 4	Nonpreferred drugs	38% coinsurance	
Tier 5	Specialty drugs	25% coinsurance	

Note: LIS (low-income subsidy). Some stand-alone Part D plans use copayments for drugs on Tier 3 while others use coinsurance; roughly 75 percent of enrollees are in plans that use copayments. The maximum cost sharing for an individual LIS beneficiary depends on several factors in addition to the drug's brond/generic status, such as whether the beneficiary receives Medicaid-funded long-term services and supports and whether the beneficiary has reached Part D's out-of-pocket threshold for catastrophic coverage.

Source: Centers for Medicare & Medicaid Services 2019a, Cubanski and Damico 2019.

spending of $218 per month (Medicare Payment Advisory Commission 2019b).

Although the LIS helps ensure access to medicines, its limits on cost sharing also give LIS enrollees weaker incentives to use lower cost drugs and make it more difficult for plan sponsors to manage enrollees' drug spending. For enrollees without the LIS, plan sponsors set cost-sharing requirements with strong incentives to select lower cost drugs (Table 5-7). For example, in 2020, the median copayment in stand-alone PDPs is $0 for preferred generics and $3 for other generics, compared with a median copayment of $42 for preferred brand-name drugs (Cubanski and Damico 2019). Cost sharing was higher still for nonpreferred drug tiers and specialty tiers.[12] For the cost-sharing structure shown in Table 5-7, the savings to an LIS enrollee from taking a generic over a brand-name drug would be just over $5 ($8.95 minus $3.60), but for the other Part D enrollees, the savings would be on average $39 ($42 minus $3). Likewise, LIS enrollees have no incentive to use a plan's preferred brand-name drug rather than other brand-name drugs because they would pay $8.95 regardless.

Plan sponsors we interviewed indicated that managing spending and prescription use of LIS enrollees was more difficult than for other enrollees. In their view, the differential between copayments for generic and brand-name drugs (about $5) did not provide enough financial incentive for beneficiaries to use generics. Likewise, charging the same copayment for all brand-name drugs gave beneficiaries no incentive to use lower cost brands. Interviewees also noted that a number of LIS enrollees seek nonformulary exceptions for brand-name drugs that have generic equivalents, requiring the plan to cover a product not normally included on its formulary. Large numbers of nonformulary exceptions tend to undermine plan sponsors' bargaining leverage in their negotiations with manufacturers for rebates. Nonformulary exceptions may be clinically warranted in some cases. However, for enrollees without the LIS who seek such an exception, they typically must pay the cost sharing of their plan's nonpreferred tier.

Interviewees also reported that managing drug spending for LIS beneficiaries was more difficult because these enrollees were more likely to use drugs in Part D's protected classes. Medicare's requirement that plans cover "all or substantially all" drugs in the six classes ensures that beneficiaries who have conditions for which drugs play a key role in treatment have broad access to coverage. However, because manufacturers know that their products cannot be excluded from plan formularies, the policy also limits plan sponsors' ability to obtain rebates on brand-name drugs. One recent study found that manufacturers provided rebates on fewer brand-name drugs in the

protected classes (13 percent vs. 36 percent of all brand-name drugs) and that the rebates they did provide were smaller (14 percent of gross costs vs. 30 percent for all brand-name drugs) (Johnson et al. 2018).

Claims data show that the generic dispensing rate (GDR)—the share of prescriptions filled with generic drugs—has consistently been lower for LIS enrollees. In 2017, LIS beneficiaries had a GDR about 5 percentage points lower than that for other enrollees (85 percent vs. 90 percent). A representative of one sponsor we interviewed noted that even though differences in GDRs may not seem large, brand-name drugs are many times more expensive than most generics, and so lower use of generics by LIS beneficiaries has a material impact on plan costs. Lower generic use may partly reflect clinical differences, such as having a condition for which all available therapies are brand-name drugs. Nevertheless, regarding therapeutic classes for which all or most drugs have lost patent protection, claims data show that LIS enrollees are less likely to use generics. For example, in 2017, LIS beneficiaries had lower GDRs than other beneficiaries for proton pump inhibitors (88 percent vs. 97 percent), statins (96 percent vs. 99 percent), and certain antidepressants (92 percent vs. 98 percent). These differences suggest that clinical factors alone cannot fully explain lower generic use among LIS beneficiaries.

Greater flexibility in formulary management

Formulary design is the key tool used by plan sponsors to manage drug benefits and affect sponsors' bargaining leverage with pharmaceutical manufacturers. The Commission expects that any policy change that requires plan sponsors to bear more insurance risk would be combined with other changes that would provide sponsors with greater flexibility to use formulary tools. In addition, the Secretary could consider other regulatory changes that would provide plan sponsors with more flexibility while maintaining beneficiary access to clinically appropriate medications.[13]

Allow plans to use a nonpreferred tier for specialty drugs

Under CMS's current guidance, plan sponsors may place drugs that cost $670 per month or more on a specialty tier.[14] Between 2007 and 2017, spending for specialty-tier drugs grew more than 10-fold—from $3.4 billion to $37.1 billion (Medicare Payment Advisory Commission 2019d). Spending for specialty-tier prescriptions made up nearly a quarter of gross Part D spending by 2017 (up from 5.5 percent in 2007), and likely an even larger share of spending after accounting for rebates and discounts.[15]

Some commercial plans have two specialty tiers (preferred and nonpreferred) to manage the use of specialty drugs. Such a tier structure could, if appropriately used, enhance patient care by providing access to specialty drugs while reducing inappropriate use. This tier structure could also encourage competition among existing specialty drugs that are therapeutic substitutes and could help encourage beneficiaries to consider using biosimilar products when they become available. Because more expensive or less clinically effective therapies could be placed on the nonpreferred tier, rather than be excluded from the formulary, this tier structure could reduce the need for nonformulary exceptions.

In February 2020, CMS proposed a policy to allow a second, "preferred" specialty tier in Part D with a lower cost-sharing amount (CMS–4190–P). CMS designed the proposal to give plan sponsors more tools to manage the drug benefit, and the Commission shares that goal. Nevertheless, the Commission noted in its comment letter that CMS's proposal may constrain plan sponsors in their design of new specialty tiers and keep them from being as effective as they could be (Medicare Payment Advisory Commission 2020a). The Commission encourages CMS to provide sponsors with greater flexibility to ensure they have meaningful tools to manage specialty-drug spending and leverage to negotiate rebates with manufacturers.

Differentiate LIS cost sharing for preferred and nonpreferred drugs

Plan sponsors, both in Part D and in the commercial market, routinely use differential cost sharing to make generics and lower cost drugs and biologics more attractive to enrollees. However, current LIS copayments provide much weaker financial incentives than those faced by other enrollees. If plan sponsors are to take on more risk for LIS enrollees, additional tools would help them better manage spending for this population.

In 2016, the Commission recommended that the Congress change Part D to modify LIS copayments to encourage the use of lower cost therapies in selected therapeutic classes (Medicare Payment Advisory Commission 2016). Those modifications could take the form of both decreases in cost sharing (e.g., zero copayments for preferred generics) and modest increases for certain nonpreferred prescriptions. To protect beneficiaries, under the recommendation, the Secretary would have authority to select therapeutic

TABLE 5–8

Illustrative example of requiring LIS beneficiaries to pay higher cost sharing for certain drugs

Drug category	Beneficiaries without the LIS	LIS beneficiaries: Current cost-sharing limit	LIS beneficiaries: Cost-sharing limit under policy
Generic	$0 copayment	$3.60*	No change*
Other generic	$3 copayment	$3.60	
Preferred drug (largely brands)	$42 copayment	$8.95	
Preferred specialty	15% coinsurance	$8.95	
Nonpreferred drug (largely brands)	38% coinsurance	$8.95	Modestly higher limits would apply*
Nonpreferred specialty	35% coinsurance	$8.95	

Note: LIS (low-income subsidy).
*If the plan's standard cost-sharing amount is lower than the limit, LIS beneficiaries pay the standard amount. For example, under current law, the actual amount that LIS beneficiaries pay for drugs on the generic tier would be $0.

Source: Cubanski and Damico 2019; CMS Office of the Actuary.

classes to which this policy would apply—classes that have generics or biosimilars available and for which substitution would be clinically appropriate.

Consistent with the 2016 recommendation, policymakers could consider allowing modestly higher cost sharing if an LIS beneficiary chooses to fill a prescription for a nonpreferred drug rather than an alternative on a preferred drug tier. (See text box on how low-income beneficiaries respond to cost sharing, pp. 146–147.) As is the case for the other Part D beneficiaries who seek a nonformulary exception, LIS beneficiaries who do so would pay the LIS copayment amount for nonpreferred tiers. Policymakers could also apply differential cost sharing to high-cost specialty drugs by allowing Part D plans to have separate preferred and nonpreferred tiers for specialty drugs. Plan formularies thus could have up to six tiers since there effectively could be two generic tiers as well as separate preferred and nonpreferred tiers for brand-name drugs and specialty drugs. The current LIS limits on cost sharing could still apply to the generic tiers and the preferred tiers; since plans must include at least one drug in each therapeutic class on a preferred tier, this policy would help ensure that LIS beneficiaries still had good access to coverage. Under this policy to include a new statutory LIS copayment amount for nonpreferred drugs and nonformulary exceptions, plans would make LIS enrollees and their prescribers aware of preferred and nonpreferred therapeutic options for the patient as well as the relevant LIS copayment amounts.

Table 5-8 provides an illustrative example of how differential cost sharing could work for LIS beneficiaries. In this example, which focuses on LIS beneficiaries who currently pay $3.60 for generics (the maximum copayment for drugs on the two generic tiers) and $8.95 for brands, the preferred drug tier (which is largely brands) and the preferred specialty tier would remain the same, but the limits for the nonpreferred drug tier (again, largely brands) and the nonpreferred specialty tier would increase somewhat. However, differential cost sharing would not apply to those LIS beneficiaries who pay no cost sharing.[16]

Give plans greater flexibility in the protected drug classes

Medicare's requirement that plans cover all drugs in the six protected classes makes it harder for plans to obtain rebates and manage drug spending. Several sponsors said that plans would have an easier time managing drug costs for LIS beneficiaries if some of the restrictions on the protected drug classes were modified. For example, one sponsor said that most drugs in some protected classes have lost their patent protection and that many enrollees can now be effectively treated with generics. However, the

How low-income beneficiaries respond to cost sharing on prescription drugs

Researchers have consistently found that cost sharing reduces overall spending on prescription drugs, with one review of the literature concluding that a 10 percent increase in cost sharing reduces overall prescription drug spending by between 2 percent and 6 percent. Some studies have found that the sensitivity to cost sharing depends on the drug and that higher cost sharing has a smaller effect on the use of more essential drugs, such as those for chronic conditions. Research has also generally found that, for people with chronic conditions such as diabetes or schizophrenia, higher cost sharing for prescription drugs is associated with higher medical costs for services like inpatient care and emergency care. Although there is a widespread belief that low-income populations may be more sensitive to changes in cost sharing, "there is little reliable evidence to support this contention" (Goldman et al. 2007).

Most of the research on the effects of prescription drug cost sharing on low-income groups has looked at the experience in Medicaid (Goldman et al. 2007).

States can charge nominal copayments of up to $4 for preferred drugs and $8 for nonpreferred drugs (Medicaid and CHIP Payment and Access Commission 2018). As of 2018, 35 states and the District of Columbia have copayments for prescription drugs, usually ranging between $0.50 and $3 per prescription (Kaiser Family Foundation 2018). Research on the introduction of state copayments has found that even modest copayments can significantly affect prescription drug spending (Goldman et al. 2007). One study of Oregon's Medicaid program found that the introduction of drug copayments did not lead to greater use of inpatient care or emergency care, even among individuals with chronic conditions (Hartung et al. 2008).

Two more-recent studies focusing on low-income populations examined the effects of modifying cost sharing for a subset of drugs, instead of applying cost sharing across all drugs. This targeted approach is more analogous to increasing cost sharing for nonpreferred drugs only. Both studies are somewhat cautionary tales.

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sponsor said that the potential savings from these generics have not been fully realized because the sponsor has had to cover several brand-name drugs that are new formulations of older medications but are not, in its view, any more effective.

The "protected class" policy was intended to ensure that beneficiaries who were transitioning from other drug coverage (e.g., Medicaid) to the Part D program would have uninterrupted access to medications in six classes. Currently, plan sponsors may apply utilization management to protected-class drugs and place therapeutic alternatives in protected classes on different cost-sharing tiers. However, because LIS cost-sharing amounts are set by law rather than by plans, the LIS enrollee does not face the same incentives to use the preferred product as other plan enrollees. More generally, the requirement to cover "all or substantially all" drugs in protected classes reduces plan sponsors' bargaining leverage with manufacturers; rebates are less easily obtained and are smaller, on average, for brand-name drugs in protected classes (Johnson et al. 2018). If LIS cost sharing were modified to allow differential copayments between preferred and nonpreferred drugs, plan sponsors would have more bargaining leverage with manufacturers for rebates.

The Commission has previously expressed support for giving plans greater flexibility with the protected classes. In 2016, we recommended removing antidepressants and immunosuppressants from the protected classes (Medicare Payment Advisory Commission 2016). In 2019, we supported a CMS proposal that would make it easier for plans to use formulary management tools in the protected classes (Medicare Payment Advisory Commission 2019a).[17] The proposal would have allowed plan sponsors to use formulary tools more broadly under specific circumstances (e.g., use prior authorization to determine whether a drug was prescribed for a protected-

How low-income beneficiaries respond to cost sharing on prescription drugs (cont.)

The first study looked at changes to the copayments for prescription drugs in the Massachusetts Medicaid program (Lieberman et al. 2014). The state initially charged $1 for generics and $3 for brands. The state then raised the copayment for most generics from $1 to $3 but kept the $1 copayment for certain targeted drug classes (antihypertensives, antihyperlipidemics, and hypoglycemics). The copayment for brand-name drugs did not change. The study found that, within the targeted drug classes, use of generic drugs increased while use of brands stayed the same. Higher generic usage was due to higher overall use in the targeted drug classes, rather than individuals switching from brands to generics. More importantly, the study found that elsewhere in the program, use of brand-name drugs increased and generic use decreased because enrollees no longer had an incentive to use generics. These findings underscore that even modest changes to cost sharing can affect patterns of prescription use. Policies to encourage Part D's low-income subsidy (LIS) beneficiaries to use preferred drugs over nonpreferred ones—largely aimed at reallocating use among brand drugs—should be careful to preserve the basic incentive to use generics instead of brands when possible.

The second study looked at the effects of eliminating copayments for generics, a popular strategy for promoting the use of generics over expensive brand medications (Stuart et al. 2017). The study was unusual for two reasons: (1) It looked specifically at Part D enrollees who received the LIS (researchers typically exclude these beneficiaries from studies on the effects of differential cost sharing since the LIS covers most of their cost sharing), and (2) the treatment and control groups were randomly assigned. The study examined LIS beneficiaries who were assigned to new Part D plans and compared those placed in plans that had free generics in two drug classes (oral antidiabetic drugs and statins) with those placed in plans that had copayments. The study did not find any significant differences in generic utilization between the two groups, suggesting that eliminating copayments on generic drugs may have relatively little effect on the LIS population. ■

class indication) while maintaining appropriate access to all or substantially all drugs in protected classes (Centers for Medicare & Medicaid Services 2019b, Kocot et al. 2019). However, due to concerns raised by stakeholders, CMS chose not to finalize its proposal.

The importance of adequate risk adjustment

Risk adjustment plays a vital role in a capitated payment system by counterbalancing plan incentives for selection and ensuring that plans receive adequate payment for covering high-cost individuals, such as Part D's LIS beneficiaries. Since capitated payments would play a larger role in a redesigned Part D benefit, ensuring that payments are properly risk adjusted is a key concern for policymakers.

It would be critically important for CMS to recalibrate the prescription drug hierarchical condition category (RxHCC) model if policymakers expanded the amount of Part D drug spending covered by capitated payments. (See text box on Part D risk adjustment, pp. 148–149.) CMS has periodically recalibrated the model to account for the effects of the Affordable Care Act of 2010, which gradually required Part D plans to cover some drug spending in the coverage gap for beneficiaries without the LIS. These revisions appear to have been successful in ensuring that payment rates for those beneficiaries remain sufficient. The transition to the new benefit structure may increase CMS's administrative burden by requiring it to recalibrate the model more frequently than it would normally. However, CMS has substantial experience with recalibration, both for routine updates and in response to policy changes, and we believe that the agency would be able to recalibrate the model to ensure adequate payments to plans.

The structure of the RxHCC model should make it feasible for CMS to recalibrate the model to account

Would Part D's risk adjusters disadvantage plans that enroll a higher share of low-income subsidy beneficiaries?

In Part D, CMS uses the prescription drug hierarchical condition category (RxHCC) model to adjust payments to reflect the health status of each plan's enrollees. The RxHCC model assigns each demographic characteristic and medical diagnosis a weight that represents its expected impact on an enrollee's overall costs. Between 2006 and 2010, CMS applied an early version of the model that used the same risk adjusters for all Part D beneficiaries. In 2011, CMS began using a revised model that split beneficiaries into five groups: low-income subsidy (LIS) beneficiaries living in the community (divided into those under 65 and those 65 and older), beneficiaries without the LIS living in the community (divided into those under 65 and those 65 and older), and beneficiaries living in long-term care facilities. These groups have distinctive drug-spending profiles, so the revised model has a separate set of risk adjusters for each group. Under the revised model, the risk adjusters for LIS beneficiaries are generally larger than the adjusters for beneficiaries without the LIS, resulting in higher payments for LIS beneficiaries.[18]

Although LIS beneficiaries have higher drug costs and plan sponsors believe it is more difficult to manage their drug utilization, the sponsors and actuaries we interviewed all said that the revised RxHCC model had improved payment rates for LIS beneficiaries and that payments for this population are now generally adequate.

The recommended reforms would result in higher capitated payments for all enrollees, with a larger impact—in dollar terms—for LIS beneficiaries. However, given the structure of the RxHCC model, we contend that CMS would be able to recalibrate the model to ensure adequate *overall* payment rates for both sets of enrollees. One concern is that, because risk adjustment models tend to underpredict very high spending and overpredict very low spending, plans that enroll a relatively high share of high-cost beneficiaries could be disadvantaged.[19] The Commission is particularly concerned about smaller plan sponsors that enroll a higher share of LIS beneficiaries.

To examine whether plan sponsors with a higher share of LIS beneficiaries are likely to be disadvantaged as a result of inadequate risk adjustment, we used 2018 claims data to compare variation in Part D's gross drug spending for LIS and other populations. We measured relative variation using the coefficient of variation (CV)—the standard deviation of individuals' annual spending divided by mean spending. A higher CV means there is more variation relative to the average. We found that although LIS enrollees have more than twice the average spending of enrollees without the LIS, relative variation in LIS spending is lower. In 2018, mean drug spending for LIS beneficiaries was $6,371 compared with $2,740 for other Part D beneficiaries (Table 5-9). However, the CV for LIS beneficiaries (280 percent) was considerably lower than for beneficiaries without the LIS (417 percent).

This difference in CVs reflects distinct patterns of prescription use and spending for these two populations. The majority of beneficiaries without the LIS used primarily low-cost generics and had relatively low spending. However, a relatively small share of these beneficiaries (3 percent in 2018) incurred spending high enough to reach the out-of-pocket (OOP) threshold. LIS beneficiaries, on the other hand, tended to have higher spending and were more likely to reach the OOP threshold: 19 percent did so in 2018.

To evaluate the potential effects of recalibration, it is useful to consider separately the two elements of higher liability that plans would incur under a restructured Part D benefit—more coverage-gap spending and catastrophic spending. We repeated our CV analysis on Part D claims but separately evaluated beneficiaries' spending below and above the OOP threshold. For LIS enrollees, average spending below the OOP threshold was $3,037, and variation around that mean was relatively low: 99 percent (Table 5-9). By comparison, enrollees without the LIS had lower average spending below the threshold ($1,909) but nearly twice as much relative variation around their mean (195 percent). This contrast suggests that as sponsors consider the additional liability that their plans would incur below

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Would Part D's risk adjusters disadvantage plans that enroll a higher share of low-income subsidy beneficiaries? (cont.)

the OOP threshold (including in the coverage gap), spending for LIS enrollees may be more predictable than spending for other enrollees. Likewise, as CMS recalibrates its risk adjusters for LIS enrollees, the agency's RxHCC model will have relatively less variation to explain below the OOP threshold than its models for other enrollees.

By comparison, catastrophic spending (spending above the OOP threshold) is less predictable than coverage-gap spending because the extreme values are influenced more heavily by use of high-priced drug and biologic treatments for less prevalent conditions, such as cancer and rheumatoid arthritis. For LIS enrollees (including those with no drug spending as well as individuals well above the OOP threshold), catastrophic spending averaged $3,306 and varied widely (a CV of 506 percent) (Table 5-9). By comparison, average catastrophic spending for the other Part D enrollees was much lower ($832). However, the relative variation around that average was more than twice as large (1,169 percent). This suggests a recalibrated risk adjustment model is more likely to underpredict very high spending incurred by beneficiaries without the LIS than beneficiaries with the LIS.

In our analysis of claims data, we found that many LIS beneficiaries reach the catastrophic phase of the benefit using medications for chronic or more prevalent conditions (Medicare Payment Advisory Commission 2016). Beneficiaries without the LIS have more extreme spending than do LIS enrollees. In 2018, of the beneficiaries who reached the OOP threshold and did not receive the LIS, 10 percent incurred more than $84,753 in gross Part D spending. Less than 5 percent of LIS beneficiaries who reached the OOP threshold reached that level of spending (data not shown), and the threshold for reaching the top 10 percent ranked by spending was $44,780 (Table 5-9). ■

TABLE 5-9

Spending varied more for beneficiaries without the LIS than for LIS beneficiaries, 2018

	Beneficiaries without LIS		Beneficiaries with LIS	
	Mean	Coefficient of variation	Mean	Coefficient of variation
All Part D beneficiaries				
Annual spending per person	$2,740	417%	$6,371	280%
Spending below the OOP threshold	1,909	195%	3,037	99%
Spending above the OOP threshold	832	1,169%	3,306	506%
Distribution of spending for beneficiaries who reach the OOP threshold				
Mean	$34,314		$23,215	
Median	16,925		14,159	
90th percentile	84,753		44,780	

Note: LIS (low-income subsidy), OOP (out-of-pocket). Spending reflects prices paid at the pharmacy (gross spending) before postsale rebates and discounts. The coefficient of variation is the standard deviation of annual spending per person divided by the mean. Enrollees were included in this analysis if they were enrolled in Part D for the full benefit year. Values include enrollees who had na claims.

Source: MedPAC analysis of Part D's prescription drug event data.

for the disproportionate impact that the reform package would have on the average capitated payments for LIS beneficiaries. The key feature that makes this possible is the use of separate risk adjusters for LIS beneficiaries versus the other Part D beneficiaries. When CMS calculates these adjusters, it implicitly accounts for any differences in the average costs of the two populations. For example, under the illustrative example shown in Table 5-6 (p. 139), recalibrated risk adjusters would ensure that average capitated payments for LIS beneficiaries increased from $139 to $289, while payments for the other Part D beneficiaries would increase from $87 to $130.

However, it is important to note that the RxHCC model is not designed to predict costs for individual beneficiaries; it aims instead to predict costs for groups of beneficiaries, like the enrollees in a health plan. As a result, while we believe that the RxHCC model could be recalibrated to provide an adequate overall level of risk adjustment for plans that serve LIS beneficiaries, the recalibrated model might nonetheless underestimate costs for certain types of beneficiaries, such as those who use very high–cost drugs. These high-cost outliers might pose a greater risk for regional PDPs and MA–PDs because, compared with large plans offered by national sponsors (for which the effects of high-cost outliers are more likely to average out), they typically have lower enrollment and thus less ability to absorb losses. For example, some regional sponsors have little or no presence in other lines of business, such as commercial coverage or Medicaid managed care, that could be used to offset unexpected Part D losses, and regional sponsors that are nonprofit organizations may have lower capital reserves.

Because CMS estimates RxHCCs using past Part D claims, the model is not intended to adjust immediately for entries of new high-priced drugs. As a result, if those new entries are not anticipated by plan sponsors, and therefore are not reflected in their bids, plan sponsors could experience costs that exceed their risk-adjusted payments (and premiums). When new therapies for hepatitis C entered the market, CMS manually modified certain RxHCCs to reflect high-priced treatments until Part D claims data for the products became available to recalibrate the risk adjustment model.

While cases like hepatitis C drugs are not likely to occur frequently, CMS may want to investigate whether the RxHCC model could incorporate major therapeutic innovations more quickly to prevent large and systematic underpayments or overpayments for a particular condition. At the same time, if Medicare were to base plan payments on risk-adjusted amounts that predict actual spending too closely, the result would differ little from using a system of cost-based reimbursement rather than one of prospective payment.

Transitional changes to risk corridors

The recommended reforms would require plan sponsors to bear more financial risk by expanding the use of capitated payments and reducing the use of cost-based payments for the LICS and reinsurance. We anticipate that, under a restructured Part D, some plans could experience spending patterns that are more variable than their historical experience based on the current plan liability.

Some stakeholders we interviewed suggest that drug spending is inherently more difficult to predict than medical spending because of uncertainties about when new drugs will enter the market, their launch prices, and the extent to which new therapies will be prescribed. Because high-priced orphan and specialty drugs have made up larger shares of new medications in the development pipeline, most interviewees thought that drug spending had grown more difficult to predict over time. In an earlier analysis, we found that between 2008 and 2012, variation in Medicare beneficiaries' drug spending had grown, but was roughly comparable with variation in medical spending by the end of the period (Medicare Payment Advisory Commission 2015). In an updated analysis, we found that variation in drug spending now exceeds that of FFS medical spending. However, variation was driven mostly by predictable spending; nearly 80 percent of spending in the catastrophic phase was attributable to beneficiaries who had catastrophic spending in the previous year, meaning that unexpected costs accounted for only about 20 percent of total catastrophic costs.

It would be very important for CMS to recalibrate the RxHCC model to ensure that plans are compensated appropriately and to discourage plan sponsors from engaging in risk selection. However, given the higher insurance risk associated with spending in the catastrophic phase of the benefit, the recalibration of the RxHCC model could be insufficient to achieve those goals, at least during a transition period. Further, plan sponsors with smaller membership size could be less able to absorb the effects of an unexpected change in the pharmaceutical market (e.g., the unanticipated launch of an expensive new medication) compared with their larger counterparts.

Part D's risk corridors limit (but do not cap) a plan's overall losses across all its enrollees when actual spending for basic benefits is higher than predicted spending. (Since Part D's risk corridors are symmetric, they also limit a plan's unanticipated profits.) In contrast to Medicare's individual reinsurance that protects plans against unexpectedly high costs incurred by individual enrollees, risk corridors provide a cushion at the plan level in the event of unforeseen high drug spending.

Currently, plan sponsors are at full financial risk if actual benefit spending is within the range of 95 percent to 105 percent of the plan's bid. (That is, a plan is fully at risk for spending up to 5 percent above its bid (losses) or 5 percent below (profits).) If actual benefit spending is either between 105 percent and 110 percent of the bid or between 90 percent and 95 percent of the bid, Medicare splits the difference with the plan sponsor between the bid and actual benefit spending 50–50. Beyond 110 percent or below 90 percent, Medicare covers 80 percent of excess benefit costs (or recoups excess profits).

If plan sponsors are to assume a greater share of spending in the catastrophic phase of the benefit, policymakers could consider making the risk corridors more generous to provide greater protection. For example, policymakers could narrow the risk corridors so that plans are fully at risk for less than 5 percent above or below their bids. Because plan bids would be higher with a restructured benefit than with the current benefit structure, a narrower corridor would help to keep the potential losses (or profits) at a level closer to what plans face today. Policymakers could also consider different risk-sharing percentages in the corridors, including greater aggregate stop-loss protection, which could be particularly valuable for smaller plans and plan sponsors that do not have the scale to self-reinsure.

Recommendations for a restructured Part D benefit

Three interrelated recommendations for restructuring Part D have evolved from the Commission's 2016 recommendations to provide a package of reforms. Under our first recommendation, the Congress would change the benefit's design to introduce an OOP cap for all Part D beneficiaries and would reallocate the financial risk of benefit spending among plan sponsors, pharmaceutical manufacturers, and the Medicare program. In the second recommendation, the Congress would make concurrent changes that would give plan sponsors greater flexibility to manage formularies and would tighten Part D's risk corridors during a transition period to the new benefit design. Under the third recommendation, CMS would facilitate greater formulary flexibility and ensure that Part D's risk adjustment system compensates plans for the higher benefit liability required under the new benefit design.

RECOMMENDATION 5-1

The Congress should make the following changes to the Part D prescription drug benefit:

- **Below the out-of-pocket threshold:**
  - **Eliminate the initial coverage limit.**
  - **Eliminate the coverage-gap discount program.**
- **Above the out-of-pocket threshold:**
  - **Eliminate enrollee cost sharing.**
  - **Transition Medicare's reinsurance subsidy from 80 percent to 20 percent.**
  - **Require pharmaceutical manufacturers to provide a discount equal to no less than 30 percent of the negotiated price for brand drugs, biologics, biosimilars, and high-cost generic drugs.**

RATIONALE 5-1

At the start of the Part D program, plan sponsors had strong incentives to manage their enrollees' drug spending because most of their revenues took the form of fixed-dollar premiums and capitated payments from Medicare. Over time, changes in law and in spending patterns have significantly reduced plans' financial liability for benefits and eroded their incentives to manage spending. Plans' small liability in the coverage gap and catastrophic phases of the benefit have led to incentives for Part D sponsors to place certain high-price, high-rebate products on their formularies. Some manufacturers find that increasing their prices allows them to offer larger rebates than their competitors and gain favorable formulary placement while paying comparatively small coverage-gap discounts. In other words, manufacturers do not bear much of the effects of their price increases as directly as they would if the discount applied in the catastrophic phase of the benefit. Meanwhile, beneficiaries pay coinsurance based on high list prices for some of those drugs, potentially reaching Part D's OOP threshold more quickly than if the

plan sponsor had instead selected lower priced therapies for their formulary. The coverage-gap discount also distorts beneficiary and plan incentives because it makes the brand-name drugs cheaper relative to generic drugs. Beneficiaries who reach the OOP threshold pay 5 percent coinsurance with no upper limit. Because Medicare subsidizes nearly 75 percent of basic benefits, the financial burden on taxpayers is likely higher than it would be if policymakers restored Part D to its original approach of using more risk-based payments with stronger incentives for plans to manage benefit spending.

The discount in the catastrophic phase could be set at a higher rate to offset other costs of the restructured benefit. Alternatively, policymakers could choose to pay for the restructured benefit through higher enrollee premiums, higher Medicare program spending, or both. The Commission chose a manufacturer discount rate of at least 30 percent to include manufacturers among the stakeholders that would bear strong direct effects of drug price increases. A 30 percent discount would also help offset what would otherwise be increases in enrollee premiums and Medicare program spending resulting from Part D's new benefit structure.

As part of our recommendation, the reduction in reinsurance payments and increase in plan liability for catastrophic spending would be phased in during a transition period. (The other elements of the new benefit structure—eliminating the coverage gap, replacing the coverage-gap discount program with a new discount program in the catastrophic phase, and adding an annual cap on beneficiary OOP costs—could be implemented without a transition.) We have suggested a transition period of four years, but policymakers could consider a shorter or longer period. A longer transition would give plans more time to adjust to the new benefit structure and allow policymakers to respond to any unexpected outcomes before the new structure is fully phased in. However, a longer transition would also leave some of the current system's misaligned incentives in place longer and potentially inhibit the entrance into the market of new Part D sponsors.

RECOMMENDATION 5-2

Concurrent with our recommended changes to the benefit design, the Congress should:

- **Establish a higher copayment amount under the low-income subsidy for nonpreferred and nonformulary drugs.**
- **Give plan sponsors greater flexibility to manage the use of drugs in the protected classes.**
- **Modify the program's risk corridors to reduce plans' aggregate risk during the transition to the new benefit structure.**

RATIONALE 5-2

The second recommendation would provide plan sponsors with stronger formulary tools with which to manage enrollees' drug spending and negotiate lower prices. It would complement the first recommendation in that the combination of greater incentives (more of Medicare's subsidy through capitated payments) and stronger tools (more formulary flexibility) could lead plan sponsors to manage overall drug spending more effectively.

Plan sponsors routinely use differential cost sharing to make lower cost drugs and biologics more attractive to enrollees. However, since maximum cost sharing for LIS enrollees is set by law and plans cannot modify those amounts, sponsors have limited ability to manage drug spending for this population. Current LIS copayments provide much weaker financial incentives to choose lower cost medications than those faced by other enrollees. In particular, LIS enrollees have no financial incentive to choose brand-name drugs on a preferred tier over an alternative on a nonpreferred tier or a nonformulary drug. Under this recommendation, plans would make LIS enrollees and their prescribers aware of preferred therapeutic options as well as the relevant LIS copayment amounts.

Under the existing protected-class policy, plan sponsors must include all drugs in six therapeutic classes on their formulary. Even though plan sponsors may place utilization management requirements on protected-class drugs, their inability to exclude products from a plan's formulary prevents sponsors from using competitive pressure among alternative drug therapies to negotiate for manufacturer rebates. In turn, plan sponsors report that manufacturers offer fewer rebates on brand-name drugs in protected classes, and when they are available, the rebates are lower, on average (Johnson et al. 2018). The Commission has also noted higher than average increases in list prices of single-source drugs within some of the protected classes (Medicare Payment Advisory Commission 2020b).

By modifying Part D's current risk corridors, Medicare could place temporary aggregate limits on the amount of risk plans bear as they transition to the restructured benefit.

RECOMMENDATION 5-3

Concurrent with our recommended changes to the benefit design, the Secretary should:

- **Allow plans to establish preferred and nonpreferred tiers for specialty-tier drugs.**
- **Recalibrate Part D's risk adjusters to reflect the higher benefit liability that plans bear under the new benefit structure.**

RATIONALE 5-3

The third recommendation consists of complementary actions that the Commission believes the Secretary should take in coordination with the changes in law described in the first two recommendations. Given the rapid growth in the introduction of and Part D spending for specialty-tier drugs, plan sponsors need new tools with which to manage those therapies. By allowing plans to set differential cost-sharing requirements between competing specialty products, plan sponsors may be able to encourage their enrollees to use lower priced therapies. Plan sponsors may also gain more leverage in negotiating rebates with manufacturers.

Under a restructured benefit, Part D plans would receive less reinsurance from Medicare and higher capitated payments. CMS would recalibrate its RxHCC risk adjustment model to reflect the new higher average plan liability.

IMPLICATIONS 5-1, 5-2, AND 5-3

Spending

- The Congressional Budget Office estimates that the combination of the Commission's three recommendations would lead to one-year program savings of greater than $2 billion relative to baseline spending and savings of greater than $10 billion over five years. Separate estimates for each recommendation are not available.

Beneficiaries

- The restructured benefit would be a simpler design than Part D's current benefit in that cost sharing would be more predictable for beneficiaries, who would no longer experience three different structures of cost sharing: one before they reach the initial coverage limit, one in the coverage gap, and one in the catastrophic phase.
- A new annual cap on OOP costs would lower cost sharing for enrollees who have high drug spending and would provide more complete financial protection for all enrollees. For beneficiaries who do not receive the LIS, the annual cap on OOP would eliminate cost barriers and improve access to medications, which in turn could increase the use of medications. The increase may enhance the health benefit of pharmaceutical care for some beneficiaries, while increasing polypharmacy could result in adverse health effects for others.
- Introducing differential cost sharing between plans' preferred and nonpreferred drugs would give LIS beneficiaries stronger financial incentives to use lower cost drugs. If beneficiaries switched to preferred therapies, those individuals would see no change in OOP spending. However, if a nonpreferred therapy was medically necessary, the beneficiary would have to pay the modestly higher copayment or pursue a tiering exception to obtain the nonpreferred therapy at a preferred (lower) copayment. Because the higher nonpreferred copayment would also apply to drugs not on a plan's formulary (nonformulary drugs), a beneficiary who obtained a nonformulary drug through the plan's exceptions process would also pay somewhat higher cost sharing than under current law. In those situations, we expect that plan sponsors would make LIS enrollees and their prescribers aware of the tier placement of the prescribed drug, preferred alternatives, and relevant LIS copay amounts.
- If plan sponsors offered a benefit with two specialty tiers (preferred and nonpreferred), beneficiaries who chose medications on the preferred specialty tier would benefit from lower cost sharing. If a nonpreferred specialty-tier product was medically necessary, the beneficiary would have to pay the higher cost sharing or pursue a tiering exception to obtain the nonpreferred product at the lower cost sharing that applied to the preferred specialty tier (or, in the case of an LIS beneficiary, the lower copayment set in law for preferred drugs).
- Part D has multiple beneficiary protections that would help ensure that all enrollees had continued access to clinically appropriate medications. One

such protection relates to CMS's formulary review that ensures broad coverage of medications. Plans must include at least two distinct drugs per class on their formularies. Beneficiaries would face somewhat higher cost sharing only if they and their prescriber selected a nonpreferred product over the preferred therapy. Under this policy change, beneficiaries would have access to a tiering exceptions process that would allow them to obtain the nonpreferred-tier drug at the lower, preferred cost sharing when the use of a nonpreferred-tier drug is medically necessary.

- The effects of our recommendations on enrollee premiums would depend on multiple factors and would vary by plan. On the one hand, plan sponsors would have more formulary tools and stronger incentives to manage their enrollees' spending. That, in turn, would tend to lower benefit costs and enrollee premiums. However, the increased generosity of the Part D benefit would tend to put upward pressure on costs and premiums. If the change in plan formularies or benefit structure resulted in more requests for exceptions and appeals cases, that could result in higher administrative costs, a portion of which would be reflected in enrollee premiums. Eliminating the coverage gap and beneficiary cost sharing in the catastrophic phase would increase the costs of Part D's basic benefit, which in turn could lead to higher enrollee premiums. However, a new manufacturer discount of 30 percent or more of catastrophic spending could offset most if not all of those higher benefit costs. If, under this policy change, enrollee premiums for basic benefits increased, a small share of beneficiaries could choose not to enroll in Part D. However, given that Medicare would continue to subsidize about 75 percent of the costs of the basic Part D benefit, we expect that most enrollees would remain in the program.

Plans

- Plan sponsors would be responsible for a larger share of catastrophic benefits than they are today, and Medicare's reinsurance payments would be smaller. Because this recommendation would reduce Medicare's reinsurance and increase plans' capitated payments, plan sponsors would bear more insurance risk for their enrollees' benefit spending. In general, we expect this approach would give plan sponsors stronger incentives to manage enrollees' spending and reduce incentives for sponsors to put high-price, high-rebate drugs on their formularies. If the recommendations are implemented, the Commission intends to monitor the aggregate amount of manufacturer rebates to observe whether the policy changes achieve their intended effect of reducing the misaligned incentives with respect to postsale rebates.
- Plan bids would be higher under the restructured benefit, and plan sponsors would receive higher capitated direct subsidy payments from Medicare. CMS would recalibrate Part D's risk adjustment system to reflect the predictably higher benefit spending in Medicare's capitated payments. Because of changes in law to close the coverage gap, CMS has experience updating its risk adjustment model on a regular basis. Under Part D's risk adjustment model, with separate risk adjusters for LIS beneficiaries, CMS would be able to recalibrate the model to account for the disproportionate impact that the reform package would have on the average capitated payments for LIS beneficiaries. In addition, a transition period would allow CMS to monitor the adequacy of risk-adjusted payments and any impact on plan sponsors' incentives for risk selection.
- Under the restructured benefit, plan sponsors would have more formulary tools to manage benefit spending, which in turn could lower basic benefit costs and enrollee premiums. By changing the LIS copay structure to add a new higher copayment for medications placed on a nonpreferred tier or for nonformulary drugs, plan sponsors would have an important new tool for managing spending for LIS enrollees. A new higher LIS copayment amount for nonpreferred or nonformulary drugs would also give plan sponsors greater leverage with manufacturers.
- With greater flexibility to manage drugs in the protected classes, plan sponsors would have more leverage to negotiate price concessions for protected-class drugs for which competition exists among drug manufacturers. Allowing plan sponsors to use two specialty tiers (preferred and nonpreferred) would provide a new tool to encourage the use of preferred therapies on a specialty tier, while at the same time giving sponsors leverage in their negotiations for rebates among manufacturers of drugs and biologics with high prices. This ability to structure competition among specialty products would allow plan sponsors to encourage the use of biosimilars (when they become available) and could facilitate

further development of biosimilar products. At the same time, if more beneficiaries sought exceptions for nonpreferred or nonformulary drugs, plans could have higher administrative costs associated with their exceptions and appeals process. That, in turn, could put upward pressure on plan bids and premiums.

- The new 30 percent manufacturer discount in the catastrophic phase could help limit growth in drug prices and offset Part D's basic benefit costs. If policymakers structured the discount rate so that it was indexed to growth in some benchmark measure of price inflation (such as in average Part D spending) and could potentially increase in later years, policymakers could consider lowering Medicare's reinsurance by the same amount as each incremental increase in the discount rate. If the discount rate increases led instead to a reduction in plan liability, that reduction could weaken plan incentives to manage spending.

- Replacing the coverage-gap discount program with a new manufacturer discount in the catastrophic phase would have a disproportionate impact on EGWPs. If EGWP sponsors continued to provide supplemental benefits that prevented or delayed enrollees from reaching the catastrophic phase of the benefit, they would receive fewer manufacturer discounts than they do now. At the same time, because CMS would need to go through the rule-making process to implement the restructured benefit, we expect employers would have time to adjust their benefit offerings or switch to providing the prescription drug benefit through a plan that is eligible for the retiree drug subsidy before facing the full financial impact of the reforms.

- The Commission believes it is important to transition to the new benefit structure over a period of several years partly out of concern for the stability of smaller MA–PDs that serve larger numbers of LIS enrollees. The reduction in reinsurance payments and increase in plan liability for catastrophic spending would be phased in so that plan sponsors could adjust to the new distribution of risk. (The other elements of the new benefit structure—eliminating the coverage gap, replacing the coverage-gap discount program with a new discount program in the catastrophic phase, and adding an annual cap on beneficiary OOP costs—would be implemented without a transition.) During the transition period, CMS would be able to monitor and evaluate plan sponsors' progress at using new flexibilities for managing benefit spending while still providing beneficiaries with appropriate access to medicines. A transition period would give policymakers time to identify and address any unexpected outcomes with the implementation of the new benefit.

- We have suggested a transition period of four years, but policymakers could consider a shorter or longer period. A longer transition would give plans more time to adjust to the new benefit structure and would allow policymakers to respond to any unexpected outcomes before the new structure was fully phased in. However, it would also leave some of the current system's misaligned incentives in place longer and potentially inhibit the entrance into the market of new Part D sponsors. Modifying Part D's risk corridors would provide greater financial protection during the transition to a new benefit structure. The enhanced protection could take the form of a tighter range around plan bids in which plans would be at full risk for their benefit spending, changes to the shares of gains or losses borne by Medicare and plans, or both. The modifications would be available to all plan sponsors. However, such measures would be especially important to smaller sponsors of regional MA–PDs that have larger proportions of LIS enrollees.

Pharmaceutical manufacturers

- Restructuring Part D's benefit to remove the brand manufacturer discount in the coverage gap and establishing a new manufacturer discount in the catastrophic phase would affect individual pharmaceutical manufacturers differently, depending on the products they make. Manufacturers of relatively lower priced products that now pay a sizable share of the coverage-gap discounts might see higher revenues because they would no longer need to discount their products in the coverage gap. Producers of higher priced products would pay proportionately more of the new discount.

- The new manufacturer discount in the catastrophic phase could potentially restrain manufacturers' incentives to increase drug prices. The discount could be more effective at restraining price increases if it were structured so that the discount rate increased if the average price of the drugs subject to the discount increased faster than a benchmark (such as

average Part D spending). However, the effects on manufacturers' pricing decisions would likely vary, depending on the manufacturer's Medicare market share and the degree of competition among therapeutic alternatives. There is also uncertainty as to whether the policy change would restrain or worsen the growth in launch prices of new therapies.

- New formulary tools would allow plan sponsors to bargain harder for higher rebates or reduce enrollees' use of products that offered low or no rebates through the use of nonpreferred tiers. For certain protected-class drugs, there could be products that would no longer be included on plans' formularies. As a result, some manufacturers could experience lower Part D revenues or diminished ability to raise prices of their products.
- A 30 percent manufacturer discount on catastrophic spending would likely constrain the profitability of new specialty drugs and potentially reduce incentives to invest in the research and development (R&D) of such products. Two key issues to consider are the magnitude of potential investment reductions in pharmaceutical R&D that may result from the policy change and the value of drugs that subsequently would not be developed (Ginsburg and Leiberman 2020). Some stakeholders contend that more investment resources are needed to pursue breakthrough drugs. Others believe that the current pool of resources already permits some projects to be funded that are of limited value. Because the new discount is more likely to apply to high-priced drugs and biologics, the policy change could steer investments in pharmaceutical R&D away from such products and toward drugs to address complicated aspects of more prevalent conditions (Gottlieb and Ippolito 2019). ■

Endnotes

1 The amount of gross prescription drug spending needed to reach Part D's OOP threshold varies by individual, depending on LIS status and the mix of brand and generic prescriptions an enrollee fills.

2 In 2020, 150 percent of the federal poverty guideline was $19,140 for an individual or $25,860 for a couple.

3 This figure is based on a volume-weighted Part D price index constructed by Acumen LLC, using prices paid at the point of sale (POS). The indexes do not reflect postsale rebates or discounts from manufacturers and pharmacies. POS prices are the relevant metric for determining when a beneficiary has reached the OOP threshold.

4 The figure ($13 billion) for low-income cost-sharing subsidies for prescriptions filled during the coverage gap is an estimate that reflects our internal algorithm to apportion claims that straddle multiple phases of the benefit.

5 Under law, Medigap policies may not cover Part D cost sharing, but they do cover cost sharing for Part B drugs.

6 Like PDPs, MA–PDs can offer either basic coverage or enhanced coverage. Almost all beneficiaries in traditional MA–PDs (about 95 percent) are in plans that offer enhanced coverage, while most beneficiaries in D–SNPs (about 80 percent) are in plans that offer basic coverage.

7 Medicare also has other types of health plans that include Part D coverage but are not classified as MA–PDs because they operate outside of the MA program. Two types of plans—Medicare–Medicaid Plans and the Program of All-Inclusive Care for the Elderly—are made up almost entirely of LIS beneficiaries, but in 2019 their share of the overall LIS population was only 3 percent.

8 The PBM market is highly concentrated, and the three largest PBMs are owned by major insurers that also compete with smaller plans in some geographic markets: CVS Caremark (owned by CVS Health, which owns Aetna), Express Scripts (owned by Cigna), and OptumRx (owned by UnitedHealth Group). Given the dominant position of the large PBMs and the importance of obtaining postsale rebates under Part D's current structure, new plan sponsors could have difficulty entering the Part D market because they face greater uncertainty about their plans' enrollment and manufacturers would be less likely to negotiate larger rebates with them. Going forward, policymakers could consider other approaches to ensure that new plan sponsors with innovative approaches to service delivery can enter the Part D market.

9 Under the RDS, Medicare provides a tax-free subsidy to an employer for 28 percent of each eligible retiree's drug costs that fall within a specified range of spending.

10 In 2018, CMS finalized a number of regulatory changes in Part D and proposed other steps to allow plan sponsors to use tools already available for managing pharmacy benefits in commercial populations. Some of those policies are consistent with the Commission's 2016 recommendations.

11 A few drug categories are excluded by statute, such as agents used for weight loss or gain, to promote fertility, for cosmetic purposes or hair growth, or for symptomatic relief of cough and colds.

12 Although plan sponsors tend to use coinsurance for nonpreferred and specialty tiers, one can get a sense of their magnitude in dollar terms because CMS prohibits plans from charging more than $100 for nonpreferred drugs and limits specialty tiers to drugs that cost more than $670, which means that the median coinsurance of 25 percent on a specialty tier drug is at least $167.50 (Centers for Medicare & Medicaid Services 2019a).

13 For example, CMS could consider granting exceptions from the requirement for plans to put two drugs per class (or type) on their formulary if over-the-counter alternatives were available or if one of the drugs that plans would normally have to cover was an extended-release version of an existing product. In 2018, a CMS proposed rule would have permitted plans to exclude extended-release versions of protected-class drugs from their formularies, but the policy changes were not finalized.

14 Most Part D plans have a specialty tier, but not all plans place every high-cost specialty drug on a specialty tier. Cost-sharing amounts on specialty tiers range from 25 percent to 33 percent of pharmacy (point-of-sale) prices. The industry does not have one consistent definition of specialty drugs, but these drugs tend to be characterized as high cost and are used to treat rare conditions, require special handling, use a limited distribution network, or require ongoing clinical assessment (Doshi et al. 2016).

15 The Congressional Budget Office found that, in 2015, manufacturer rebates averaged 10.5 percent for specialty drugs compared with 28.4 percent for nonspecialty brand-name drugs (Congressional Budget Office 2019).

16 For example, differential cost sharing would not apply to beneficiaries who receive Medicaid nursing home care. These beneficiaries are typically required to use all their income—

except for a very modest personal need allowance (often $30 per month) and a spousal allowance, if applicable—to help pay for their care, which is why the LIS fully covers their cost sharing.

17 CMS's proposal would have established additional exceptions to allow Part D sponsors to (1) implement broader use of prior authorization and step therapy requirements for protected-class drugs, including to determine use for protected-class indications; (2) exclude a protected-class drug from a formulary if the drug was a new formulation of an existing single-source drug or biological product, regardless of whether the older formulation remained on the market; and (3) exclude a protected-class drug from a formulary if the price of the drug increased beyond a certain threshold over a specified period. (These exceptions from the protected-class policy would not have superseded other Part D formulary requirements, such as plan sponsors' obligation to cover two distinct drugs in each drug class.)

18 For example, the base payment rate in 2020 for a 73-year-old female who lives in the community is $383 for an LIS beneficiary and $247 for a beneficiary without the LIS. In addition, the added payments based on diagnosis codes are often higher for LIS beneficiaries: If the same 73-year-old also has diabetes without complications, Medicare will pay an additional $332 for an LIS beneficiary and $280 for a beneficiary without the LIS.

19 However, the Commission has consistently found that, under the MA program's similar model for risk-adjusting payments (the CMS–hierarchical condition category, or CMS–HCC, model), special needs plans, which serve certain types of high-cost beneficiaries, have higher profits than MA plans that serve a broad range of beneficiaries (Government Accountability Office 2013, Medicare Payment Advisory Commission 2020b).

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CHAPTER 6

Separately payable drugs in the hospital outpatient prospective payment system

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Separately payable drugs in the hospital outpatient prospective payment system

Chapter summary

CMS has defined the unit of payment in the hospital outpatient prospective payment system (OPPS) as a primary service (the reason for the visit) coupled with the ancillary items provided with the primary service. That is, the OPPS typically packages the cost of ancillary items into the payment rate of the related primary service. This approach contrasts with a fee schedule in which each service (both primary and ancillary) has a separate payment. Combining a primary service and related ancillary items into a single payment unit encourages efficiency because the combination of inputs used to treat a patient determines whether the provider experiences a financial gain or loss. In this chapter, we consider an exception to this general policy in the OPPS: separately payable drugs. Although we are focusing on separately payable drugs, the issues we consider in the chapter have broader implications.

Although packaging ancillary items has the benefit of encouraging efficiency, not all ancillary items should be packaged. If the OPPS packaged ancillary items that are costly or infrequently provided with a particular primary service, the financial risk to hospitals could be excessive. By volume, the OPPS treats most drugs as packaged items. However, the OPPS provides payments for some relatively high-cost drugs that are separate from primary services. The OPPS has two distinct policies for paying for these drugs: pass-through drugs and separately payable non-pass-through (SPNPT) drugs. The pass-through program is intended to provide adequate payment to hospitals

In this chapter

for drugs that are relatively costly and new to the market. In contrast, the SPNPT program is intended to provide adequate payment for relatively high-cost drugs that are already established in the drug market. Total Medicare spending (combined program spending and beneficiary cost sharing) for pass-through drugs and SPNPT drugs has grown rapidly, increasing from $5.1 billion in 2011 to $12.9 billion in 2018. Most of that growth in drug spending—82 percent—was for cancer treatment drugs.

For a drug to be granted pass-through status, it must be new to the market, and it must have costs that exceed several thresholds relative to the OPPS payment rate of the associated service. By statute, drugs can have pass-through status for two to three years. For a drug to have SPNPT status, it must have costs per day that exceed a threshold ($130 in 2020) and it cannot be a "policy-packaged" drug, which is a drug in a category that CMS has determined is always packaged with the associated service. The categories of policy-packaged drugs include anesthesia drugs; drugs, biologics, and radiopharmaceuticals that function as supplies in diagnostic tests or procedures; and drugs and biologics that function as supplies in surgical procedures.

Packaging drugs into payment bundles provides a strong incentive for providers to be efficient. However, packaging all drugs can put providers at excessive financial risk, which can lead them to avoid infrequently used or high-cost drugs and adversely affect access to treatments that may improve patient care, which, in turn, can adversely affect incentives for drug innovation. At the same time, paying separately for drugs creates distortions in payments, and these distortions can lead to overuse of high-cost drugs and shift financial pressure from providers to Medicare. In addition, separate payments for drugs reduce price competition among manufacturers, which can lead to greater drug price inflation. Therefore, Medicare must be judicious concerning separately payable drugs and balance the desire to promote innovation with the need to maintain pressure on providers to be efficient.

The current criteria for both pass-through drugs and SPNPT drugs have been in place for more than 15 years. The Commission is concerned that the criteria for eligibility under both policies do not strike an appropriate balance between promoting access to innovative treatments and maintaining pressure on providers to be efficient. In particular, we are concerned about the rising cost of Part B drugs, and these policies for separately payable drugs do little to discourage high launch prices set by drug manufacturers or excessive use by providers. Both policies use cost criteria to identify drugs for program eligibility. The cost criteria are different between the programs, but we are concerned that both allow eligibility for drugs that could be packaged without placing excessive financial risk on hospitals. Also, neither policy requires drugs to be clinically superior to competing drugs, even

though a requirement for clinical superiority implicitly encourages innovation. As a result, Medicare could pay separately for a drug no more effective than an existing product, even when the cost of the existing product is reflected in the OPPS payment. This possibility could result in Medicare paying twice for a drug.

We reviewed criteria used to identify separately payable drugs in several payment systems for hospital services: the Medicare OPPS, the Medicare inpatient prospective payment system, and the ambulatory patient group system developed by 3M™ Health Information Systems. Taken together, these three systems use four criteria for identifying separately payable drugs:

- The drug must be new to the market.
- The cost of the drug must be high in relation to the payment rate of the associated procedure.
- The dollar cost of the drug must be high.
- The drug must show clinical superiority over other drugs with a similar therapeutic use.

All of these criteria could be used in the OPPS. However, no payment system combines the use of all four of these criteria, and the use of all four could be overly stringent.

We emphasize that the purpose of this analysis is to evaluate potential criteria for identifying drugs that should be separately payable in the OPPS. The Commission will provide further analysis to determine the specific criteria that should be used and the parameters of those criteria. At the present stage, we are certain that an effective system of separately payable drugs should have two features:

- Some drugs should be paid separately because they are not ancillary. These drugs are the purpose for a visit, are high cost, treat a condition, and are usually administered by infusion. Many of these drugs are for cancer treatment, but some, such as infliximab for treatment of autoimmune disorders, treat other conditions. Separate payment for these drugs is consistent with the policy in the ambulatory patient group system.
- Drugs should show clinical superiority over other drugs to have separately payable status. A clinical superiority requirement is vital. Without one, as noted above, Medicare could pay separately for a drug no more effective than an existing product, even when the cost of the existing product is reflected in the OPPS payment. This situation results in double payments by Medicare.

In future work, we will perform analyses to determine other criteria for identifying drugs that should be separately payable. We will also perform analysis to determine the parameters for those criteria. ■

Background

The unit of payment in the hospital outpatient prospective payment system (OPPS) is the primary service (the service that is the reason for the visit, such as a clinic visit or a device implant) coupled with the ancillary items that are provided with and adjunctive to the primary service (such as a diagnostic X-ray during a clinic visit). The OPPS packages the ancillary items with the related primary service into a single payment bundle. The rationale for packaging ancillary items rather than paying separately for them is to create an incentive for hospitals to identify the most efficient way to provide a primary service. The packaging of ancillary items contrasts with a fee schedule in which providers receive a separate payment for each service provided—the primary service and the ancillary items.

The packaging of ancillary items does not mean that OPPS payments do not reflect the cost of packaged ancillaries because the payment rates for primary services reflect the costs of the packaged items. For example, if a packaged ancillary costs $20 and is provided 50 percent of the time for patients who receive a particular primary service, then $10 (50 percent of $20) is included in the estimated cost for the primary service when setting the payment rate. A simple example of how packaging works under the OPPS is a case of someone having a bad cough with chest discomfort and congestion. If this person goes to an outpatient clinic of a hospital, the physician might order a chest X-ray to check for pneumonia. In this case, the visit to the clinic would be the primary service, while the chest X-ray, an ancillary service, would be packaged with the primary service.

In the OPPS, CMS identifies services using Healthcare Common Procedure Coding System (HCPCS) codes. CMS creates a payment bundle by combining the HCPCS code of the primary service with the HCPCS codes of the packaged ancillary items. CMS collects the HCPCS codes of the primary services into ambulatory payment classifications (APCs), which are groups of services that have similar clinical characteristics and costs. For each APC, CMS determines a payment rate that is based on the geometric mean cost of all the services in the APC.[1] All of the primary services in an APC have the same payment rate.

Although packaging ancillary items encourages efficiency by giving hospitals a financial incentive to consider all of the input costs related to the delivery of primary services, not all ancillary items should be packaged. If the OPPS packaged ancillary items that are expensive or infrequently provided with a particular primary service, the financial risk to hospitals (and the risk of stinting on care) would be excessive. For example, if the OPPS packaged a $500 drug that is provided 1 percent of the time with the primary services in an APC, the payment rate for this primary service would include only $5 for this drug. That is, the difference between the cost of the drug and how much of its cost is reflected in the payment rate of the related service would be $495.

A category of ancillary items that has grown in importance in the OPPS is drugs covered under Medicare Part B. By volume, the OPPS treats most drugs as packaged items because their cost is low enough that packaging does not pose a high financial risk. However, through statute and through CMS regulatory action, the OPPS has two policies for paying some drugs separately from primary services: pass-through drugs and separately payable non-pass-through (SPNPT) drugs. At times, we refer to these two groups collectively as "separately payable drugs." Each pass-through drug and each SPNPT drug has its own APC and payment rate. From 2011 to 2018, total Medicare spending (combined program spending and beneficiary cost sharing) for pass-through and SPNPT drugs increased from $5.1 billion to $12.9 billion.[2] Most of that growth in drug spending—82 percent—was for cancer treatment drugs, and the growth reflects strong increases in volume and prices.

As we consider which drugs should be paid separately and which should be packaged, we should be aware that not all drugs are ancillary items. In situations in which receiving a drug is the reason for the patient visit, the drug is not ancillary. These drugs are usually very expensive, are used to treat medical conditions, and are usually administered by infusion. Many of these drugs are used to treat cancer. Because of their high cost and because they are not ancillary, these drugs should be separately payable.

Existing policy for pass-through drugs

The Congress established pass-through drugs through Section 1833(t)(6) of the Social Security Act. Before CMS implemented the OPPS, there was concern that data on the cost of new drugs would not be available when setting the APC payment rates. Consequently, providers could be underpaid for these new drugs because the cost

TABLE 6-1 **The programs for pass-through drugs and separately payable non-pass-through drugs have important differences, but neither requires clinical superiority**

Program feature	Pass-through drugs	Separately payable non-pass-through drugs
New to market	Required	Not required
Time limit	Two to three years	No limit
Cost	Cost must exceed three thresholds related to primary service	Cost must exceed $130 per day
Clinical superiority	Not required	Not required

Source: Final rule regulations on the hospital outpatient prospective payment system from CMS.

of those drugs would not be reflected in the APC payment rates, which could adversely affect the use of those drugs and, thus, be a disincentive to innovation. As a result, the Congress established pass-through payments for new drugs that have high costs relative to the payment rates of their associated primary services' APCs. Pass-through payments are additional payments that providers receive above the value of the drugs that are packaged into the payment rate of a service when the providers use a pass-through drug. To implement the statute, CMS established requirements for a drug to have pass-through status:

- The item must be new, meaning that payment for the drug was not being made as of December 31, 1996.
- The cost of the drug is not insignificant in relation to the OPPS payment rate for the related service (or group of services). CMS has determined that drug costs are not insignificant if they meet all of these thresholds:
  - The estimated average reasonable cost of the drug exceeds 10 percent of the APC payment amount for the service related to the drug.
  - The estimated average reasonable cost of the drug exceeds the drug portion of the APC payment amount for the related service by at least 25 percent.
  - The difference between the estimated reasonable cost of the drug and the drug portion of the APC payment amount for the related service must exceed 10 percent of the APC payment amount for the related service.

Because the purpose of the pass-through program is to provide adequate payment for new, relatively costly drugs while CMS collects the necessary cost data for including the cost of these drugs in the APC payment rates of the related service, pass-through status is time limited. A drug can have pass-through status for two to three years. Despite requirements that pass-through drugs meet three cost thresholds, it is possible that relatively low-cost drugs, which arguably pose minimal financial risk to hospitals, can become pass-through drugs. For example, Lumason—a contrast agent used in ultrasound imaging—has pass-through status and costs about $23 per day.

Existing policy for separately payable non-pass-through drugs

The program for SPNPT drugs exists from a combination of legislation and a regulatory decision by CMS. The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) defined specified covered outpatient drugs (SCODs) and mandated separate payment for them in the OPPS. The MMA defined SCODs as drugs that had pass-through status before January 1, 2003. The MMA also requires that payment for SCODs from 2006 forward be equal to the average acquisition cost for the drug, subject to adjustments for overhead costs. CMS has used average sales price (ASP) as the basis of payment for SCODs, with adjustments to account for overhead costs that CMS has varied over time.

Through regulation, CMS established a policy that created SPNPT drugs: SCODs plus other drugs that are not SCODs but have costs per day that exceed a cost threshold ($130 in 2020). CMS adjusts this cost threshold each year using the producer price index for pharmaceutical preparations. However, CMS has established that certain

drugs must be packaged if they do not have pass-through status, which means they cannot be SPNPT drugs. CMS refers to these drugs as policy-packaged drugs. These drugs include anesthesia drugs; drugs, biologics, and radiopharmaceuticals that function as supplies in diagnostic tests or procedures; and drugs and biologics that function as supplies in surgical procedures.

The SPNPT program is distinct from the pass-through program in three important ways (Table 6-1). First, the SPNPT program is for established drugs, while the pass-through program is for new drugs. Second, the SPNPT program has no limit on how long a drug can hold SPNPT status, while the pass-through program limits eligibility to two to three years. Third, the cost requirements are very different between these two programs because pass-through drugs have to have costs that exceed three thresholds related to the payment rate of the associated service and SPNPT drugs simply have to exceed a cost per day threshold. Neither program requires drugs to show clinical superiority over other drugs.

Identifying drugs that should be separately payable in the OPPS

Packaging drugs into payment bundles provides a strong incentive for providers to be efficient. However, packaging all drugs can put providers at risk for substantial financial loss, which can lead them to avoid rarely used or high-cost drugs and adversely affect access to treatments that may improve patient care, which, in turn, can adversely affect incentives for drug innovation. At the same time, overly lenient criteria for separately payable status can lead to overuse of separately payable drugs and shift financial pressure from providers to Medicare. In addition, separate payments for drugs reduces price competition among manufacturers, especially new, separately payable drugs versus established drugs that may be packaged, which can lead to greater drug price inflation. Therefore, Medicare must be judicious concerning separately payable drugs and must balance a desire to promote access to innovative treatments with the need to maintain pressure on providers to be efficient.

The current criteria for both pass-through drugs and SPNPT drugs have been in place for 15 years. We are concerned that the criteria for eligibility in both programs do not strike an appropriate balance between promoting innovation and maintaining appropriate pressure on providers. Both programs use cost criteria to identify drugs for program eligibility, but we are concerned that both can allow separately payable status to drugs that could be packaged without placing excessive financial pressure on hospitals. In particular, the Commission is concerned about the rising cost of Part B drugs, and these policies for separately payable drugs do little to discourage either high launch prices set by drug manufacturers or excessive use by providers. In part, our concern stems from the fact that Medicare spending on separately payable drugs in the OPPS has rapidly increased, from $5.1 billion in 2011 to $12.9 billion in 2018.

Under the pass-through program, there is a risk of allowing separately payable status for low-cost drugs that could be packaged because there is no requirement that a drug's cost must exceed a dollar threshold to be a pass-through drug. There is evidence that low-cost drugs do become pass-through drugs, such as the example of Lumason discussed earlier. Under the SPNPT program, there is no requirement that a drug's cost must be high in relation to the payment rate of the associated service. We are also concerned that neither program requires drugs to be clinically better than competing drugs, even though a requirement for clinical superiority implicitly encourages innovation. As a result, Medicare could pay separately for a drug no more effective than an existing product, even when the cost of the existing product is reflected in the OPPS payment. This situation results in Medicare making a double payment.

We seek to develop a program for separately payable drugs in the OPPS that improves on the two current programs. To identify criteria that could be used to determine which drugs should be separately payable, we assessed the criteria for separately payable drugs used in several payments systems. These payment systems include the OPPS, the inpatient prospective payment system (IPPS) in the Medicare program, and the ambulatory patient group (APG) system developed by 3M™ Health Information Systems (3M HIS). Referring to this assessment, we discuss whether each of these criteria would be appropriate for the OPPS.

Payment systems for hospital services use four criteria to identify separately payable drugs

We reviewed papers by analysts at 3M HIS that describe the features of the APG system, which served as a model

for the APC system that CMS uses in the OPPS (3M Health Information Systems 2019, Averill et al. 1993, Goldfield et al. 2008). These papers indicate that, during the development of the APG system, 3M HIS considered, but did not implement, an elaborate system in which decisions to package ancillary items (including drugs) would be based on the cost of the ancillary item in relation to the cost of the associated service and how often the ancillary item is used with the associated service (Averill et al. 1993). 3M HIS also considered, and implemented, a less complicated system that paid separately for ancillary items that 3M HIS considered costly without consideration of the cost of the associated service. This system has resulted in the packaging of all drugs except those that are administered by means of infusion and constitute the reason for a visit, which are paid separately. The separately paid drugs are predominantly chemotherapy drugs.

We have already discussed the criteria for eligibility for the two programs for separately payable drugs in the OPPS, pass-through drugs and SPNPT drugs. A summary of these criteria includes the following:

- Pass-through drugs—Must be new to the market; must have costs relative to the payment rate of the associated service that exceed three thresholds
- SPNPT drugs—Must have cost per day that exceeds $130; cannot be policy-packaged drugs (largely drugs that function as supplies in a primary service)

In the IPPS, the new-technology add-on payment (NTAP) program provides separate payment for new drugs and devices that meet several criteria. For a drug to qualify for NTAP status, it must be new to the market, its cost relative to the payment rate of the applicable diagnosis related group must exceed a threshold determined by CMS, and it must show substantial clinical improvement (clinical superiority) over other drugs.[3]

In summary, the criteria that the APG system, the OPPS, and the IPPS use or considered using to determine whether drugs should be separately paid include the following: the drug's cost must be high in relation to the payment rate of the associated service, the drug has a high dollar cost, the drug must be new to the market, and the drug must show clinical superiority over competing drugs. We will consider each of these criteria in our effort to identify the criteria that drugs should meet to be eligible for separate payment under the OPPS.

Cost of drug relative to the payment rate of the associated service: Precise but complicated

The benefit of using the cost of a drug relative to the payment rate of the associated service or services as a criterion is that, for a given drug, there are situations for which packaging is reasonable and other situations for which separate payment is beneficial. Using the cost of the drug relative to the payment rate of the associated service, we can identify these different situations. If a drug is used frequently with different services, the cost of the drug relative to the payment rates of the associated services can vary. In some cases, the cost of the drug may be high relative to the payment rate. In these cases, it may be beneficial to pay separately. In other cases, the cost of the drug may be relatively low. In these cases, packaging the drug is likely to be reasonable.

A disadvantage of using cost relative to the payment rate of the associated service is the potential for complication and confusion. A drug could be packaged when used with some services and paid separately when used with others, which could be confusing for hospital staff and for claims processors.

Calculation of the cost of a drug in relation to the payment rate of the associated service uses the price of the drug, how frequently the drug is used with the associated service, and the payment rate of the associated service. Consider a situation in which a drug has a cost of $300 and is used with a service that would have a payment rate of $300 if the drug is paid separately:

- If this drug is used 5 percent of the time with this service, packaging the drug would add $15 (0.05 × $300) to the payment rate for the service (for a total payment of $315). In this case, it is reasonable to pay separately for the drug because, if the drug is packaged, the difference between the cost of the drug and the amount of the drug cost included in the payment rate of the associated service is $285, which is 95 percent of the payment rate for the service.
- Conversely, if this drug is used 95 percent of the time with this service, packaging the drug would add $285 to the payment rate for the service (for a total payment of $585). In this case, it is reasonable to package the drug because the difference between the drug cost and the amount of the drug cost included in the payment rate of the associated service is just $15, which is only 5 percent of the payment rate for the service.

This example suggests a formula that could be used to determine whether hospitals face excessive risk if a drug is packaged:

> [(cost of drug) – (percentage of time drug used with service) × (cost of drug)]/(payment rate for service).

If the result of this formula is greater than some percentage, such as 10 percent, then it would be reasonable to pay separately for the drug. If it is less than the percentage, then it would be reasonable to package the drug.

This formula is similar to the formula that the Commission uses to calculate margins for evaluating appropriate updates to Medicare payment rates. The numerator is the difference between the cost of a drug and the portion of the payment for a service that is for that drug. The denominator is the total payment for the service. The formula indicates the loss that a hospital would experience each time it used a drug that is packaged. Note that because the drug cost is packaged into the payment rate of the associated service, the provider would receive an implicit payment for the drug even when the drug is not used with the service.

High dollar cost per day: Straightforward but can be imprecise

The benefit of a requirement that a drug have a high cost is that it is straightforward and uncomplicated. If a drug is determined to be high cost—for example, the cost per day exceeds a dollar threshold—it is paid separately. Otherwise, it is packaged. This criterion presents a dichotomous situation, which is different from a criterion that requires a drug to have high cost in relation to the associated service, which can produce situations in which a drug is sometimes packaged and sometimes paid separately.

One disadvantage of a requirement that a drug be high cost is that it can be somewhat imprecise. Some drugs would have separately payable status even though packaging the drug would not put excessive financial pressure on hospitals. For example, if the OPPS paid separately for all drugs that have a cost of more than $130 per day, a drug that cost $140 per day would be paid separately. If this drug were packaged with a procedure that had a $10,000 payment rate, the hospital would not be under excessive financial risk because the cost of the drug would be small relative to the payment rate of the procedure.

A second disadvantage of this cost requirement is that it encourages manufacturers to set high prices or at least prices just above the cost per day requirement.

New to the market: Ensures adequate payment for new drugs and supports innovation

Being new to the drug market is a requirement for a drug to be eligible for the pass-through drug program and the NTAP program (which includes both drugs and devices). The purpose of these programs is to ensure adequate payment for new technology because of concerns that the necessary cost and use data are not available to include new drugs in the payment rates of the associated services. If the cost of new drugs is not reflected in payment rates, hospitals could choose not to use these new drugs, and patients' access to innovative new treatments could be diminished. Therefore, a program of separate payment for some new drugs is beneficial for adequate payment and access to innovative products. However, the duration of separate payment should be limited to the length of time needed to collect the necessary data for including the cost of new drugs in the payment rates of the associated services, generally two to three years. When the necessary cost and use data are available for including new drugs in the payment rates for the associated services, whether these drugs should be packaged or separately payable should be reconsidered along with the other established drugs.

Clinical superiority: Prevents double payments and increases incentives for innovation

Given the high threshold for reducing the financial incentives of bundled payments by carving out drugs (or other items or services), an important factor in determining whether a drug should be separately payable is that it shows clinical superiority over drugs that have similar therapeutic uses. Without a clinical superiority criterion, the Medicare program could pay separately for drugs that are not clinically better than drugs that are packaged. This situation would result in double payments by Medicare: a payment for the cost of the packaged drug and a distinct payment for the separately payable drug. Also, incentives to produce innovative drugs would be increased if drugs had to show clinical superiority to obtain separately payable status.

In the NTAP program, a drug demonstrates clinical improvement if it meets any one of the following criteria:

- The drug offers a treatment option for a patient population unresponsive to, or ineligible for, other available treatments.
- The drug offers the ability to diagnose a medical condition in a patient population for which that

medical condition is otherwise undetectable or offers the ability to diagnose a medical condition earlier in a patient population than allowed by other methods, and use of the drug affects the management of the patient.

- Use of the drug improves clinical outcomes relative to other drugs, such as:
  - a reduction in at least one clinically significant adverse event, including a reduction in mortality or a clinically significant complication;
  - a decreased rate of at least one subsequent diagnostic or therapeutic intervention (for example, due to reduced rate of recurrence of the disease process);
  - a decreased number of future hospitalizations or physician visits; or
  - a more rapid beneficial resolution of the disease process including, but not limited to, a reduced length of stay or recovery time, an improvement in one or more activities of daily living, an improved quality of life, or a demonstrated greater medication adherence or compliance.
- The totality of the circumstances otherwise demonstrates that the drug substantially improves, relative to other drugs, the diagnosis or treatment of Medicare beneficiaries.

CMS established a similar list for pass-through devices in the OPPS, which includes two additional possibilities: (1) decreased pain, bleeding, or other quantifiable symptom and (2) reduced recovery time.

The clinical superiority criteria from both the NTAP and pass-through device programs could be used in the OPPS to determine clinical superiority for drugs, and we believe that drugs that meet the requirements under either program would demonstrate true innovation.

However, implementing a clinical superiority criterion necessitates addressing what to do when drugs with similar therapeutic purposes are clinically beneficial in different ways. Consider a situation where two different drugs (Drug A and Drug B) treat the same condition, but Drug A is better than Drug B in a particular clinical attribute (perhaps it results in fewer adverse events) while Drug B is better than Drug A in a different clinical attribute (more rapid resolution of the disease process). There are at least two approaches for addressing this issue:

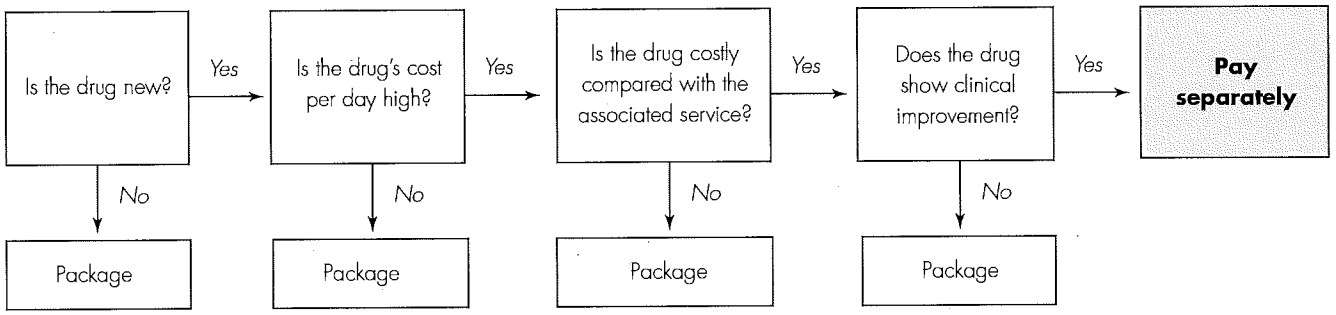
- Among drugs that have similar therapeutic uses, identify one and only one drug as being clinically better than the others. This approach would provide clarity about which drug in a given class is considered the best drug, but it may create situations where a drug has been identified as the best in its class while other drugs in the same class perform better in some clinical aspects.
- If a drug is clinically better than other drugs in its therapeutic class in *at least one clinical measure*, allow it to have separately payable status even if another drug in the same class is better in a different clinical measure. This approach would allow both Drug A and Drug B from the above example to be separately payable drugs.

Considering the criteria used in various Medicare payment systems for the OPPS

If a payment system required a drug to satisfy all four criteria that we discussed in the previous section to qualify for separately payable status, Figure 6-1 illustrates how the decision for separately payable status would work in practice. We do not know of a payment system that requires a drug to meet all four of these criteria to qualify for separately payable status. Therefore, a payment system that requires a drug to meet all four of these criteria would likely be more restrictive than any policy currently in use.

As a starting point in identifying drugs that should be separately payable in the OPPS, recall that the OPPS creates payment bundles by packaging the cost of ancillary items into the payment rates of primary services. While most drugs are ancillary items, some drugs are the reason for outpatient visits and are not ancillary. These drugs are expensive, dominate the cost of the visit, are used to treat medical conditions, and are usually administered by means of infusion techniques. Many of these drugs treat cancer, but some, such as infliximab for autoimmune disorders, treat other conditions. Because these drugs are not ancillary items, they should be separately payable. Paying separately for these drugs would be similar to the policy under the Enhanced Ambulatory Patient Group (EAPG) system—the most recent version of the APG system—

FIGURE 6–1 **Possible decision criteria for identifying separately payable drugs**



which pays separately for all infused drugs and packages all other drugs (3M Health Information Systems 2019).[4]

For the other drugs that are ancillary, the Commission intends to develop a program of separately payable drugs under the OPPS that is different from the two programs currently in use. The four criteria that we discussed in the previous section can serve as a starting point for identifying the criteria for an effective system, but we need to determine which of those criteria to use, then determine the parameters for the criteria selected.

Drug must be new to the market

The benefit of a requirement that a drug has to be new to the market is that it can increase incentives for drug manufacturers to produce innovative new products. However, allowing separate payments only for new drugs could adversely affect use of expensive drugs that are already on the market. Therefore, an important question related to this criterion is, what should be done about drugs that are already on the market? Options include:

- Implement a "new" criterion but let established drugs keep their current status; they are either packaged or paid separately under existing rules.
- Implement a "new" criterion and package all drugs that are already on the market. This option could be implemented immediately or a transition period could be used in which established drugs keep their current status for a limited period (two to three years), then package them.
- Do not use a "new" criterion and subject established drugs to the same criteria for separately payable status as new drugs.

Analysis is needed to determine the best option. If we find that most of the established drugs that are currently separately payable would be in the category of the expensive, nonancillary drugs that we have already designated as separately payable, then a "new" requirement for ancillary drugs would be reasonable because there would be few existing separately payable ancillary drugs affected by the policy.

Drug must have a high dollar cost

Drugs that have a low cost per day should be packaged because packaging them would not expose hospitals to excessive financial risk. Therefore, we assert that a separately payable drug should have a cost per day that exceeds a dollar threshold. A question that obviously must be answered is: At what level should we set the cost per day threshold?

The program for SPNPT drugs has a threshold of $130 per day for 2020, and CMS updates this threshold for drug price inflation each year. The Congress established the initial threshold for SPNPT drugs at $50 per day for both 2005 and 2006 in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003. CMS has updated the initial $50 threshold for drug price inflation each year beginning in 2007. At this time, we are not sure whether the threshold used by CMS is appropriate because

it is not based on empirical evidence. The Commission will do an empirical analysis to determine an appropriate threshold. The threshold that is selected should be adjusted each year based on inflation.

Drug's cost must be high relative to the payment rate of the associated service

CMS applies this criterion in the pass-through drug program by requiring pass-through drugs to have costs that exceed three thresholds in relation to the payment rate of the associated service. In relation to the cost per day criterion, drug cost in relation to the associated service is more complex because it includes three variables rather than one: cost of the drug, payment rate of the associated service, and how frequently the drug is used with the associated service. A useful method for determining whether the cost of a drug is high in relation to the payment rate of the associated service is to calculate the difference between the cost of the drug and how much of that cost would be reflected in the payment rate of the associated service if the drug were packaged. This difference indicates the loss a hospital would experience each time it uses the drug (note that because the drug is packaged, the provider receives an implicit payment for the drug when it does not use it). That difference would be compared with the payment rate of the associated service. A formula that represents this comparison is the following:

> [(cost of the drug) – (percentage of time drug is used with associated service) × (cost of the drug)] / (payment rate of associated service)

If the result of this equation is greater than some percentage, such as 10 percent, then it would be reasonable to pay separately for the drug. If it is less than the percentage, then it would be reasonable to package the drug.

Drug must show clinical superiority

The Commission asserts that clinical superiority is a necessary requirement for a new drug to be granted separately payable status. Without a clinical superiority requirement, a new drug could become separately payable even though it has no clinical benefit over packaged drugs that have similar therapeutic uses. Under this scenario, Medicare would make double payments when a hospital uses the separately payable drug, one for the packaged drug and one for the separately payable drugs. Moreover, requiring clinical superiority for new drugs would provide incentive for drug innovation.

A clinical superiority requirement would compare the performance of a drug with drugs that have similar therapeutic uses. If the drug is clinically better in some way, such as it resolves the disease process faster, then the drug can be separately payable. The NTAP in the IPPS and the pass-through device program in the OPPS have clinical superiority requirements, and the two programs have similar, but slightly different, options for an item to indicate clinical superiority. Because the NTAP program encompasses both devices and drugs while the pass-through program encompasses only devices, the options for showing clinical superiority in the NTAP program are likely a better fit for determining clinical superiority among drugs in the OPPS.

While use of a clinical superiority criterion is straightforward to apply if only new drugs can be separately payable, it becomes more complicated if established drugs also are allowed to be separately payable, for two reasons. First, a clinical superiority requirement is intended to spur innovation (stated earlier), and it would be logically inconsistent to apply such a requirement to drugs that have already been introduced to the market. Second, it would make the assessment of which drugs are clinically superior more costly and complicated. Consider a class of drugs that has one new drug and five established drugs. If only new drugs can be separately payable, an assessment for clinical superiority would require only a comparison of the new drug with each of the five established drugs. In contrast, if both new drugs and established drugs can be separately payable, an assessment for clinical superiority would require each drug to be compared with all the other drugs in the class.

How long should a drug be separately payable?

Should there be a time limit for how long a drug can be separately payable, or should drugs be allowed to hold separately payable status indefinitely? The two programs for separately payable drugs in the OPPS have different rules on this issue. The pass-through program limits a drug to pass-through status for two to three years, while the SPNPT program allows a drug to hold that status indefinitely. Possible approaches for a new program of separately payable drugs in the OPPS include:

- Allow only new drugs to be separately payable and limit their time. After their time expires, they are

packaged. This approach can spur incentives for innovation.

- Allow only new drugs to be separately payable, but allow them to hold that status until manufacturers produce a new drug that is clinically superior. This approach may further spur incentives for innovation because the length of time as separately payable is not definite.
- Allow both new drugs and established drugs to have separately payable status. We could classify drugs by therapeutic use. In each therapeutic class, we would determine whether each drug is better than the other drugs in its class in at least one measure of clinical performance. This approach would allow for more than one drug in a therapeutic class to be separately payable.

Summary

Because of the benefits of packaging, the Commission encourages packaging drugs to the fullest extent without subjecting hospitals to excessive financial loss. In other words, the Commission would like a system that limits separately payable drugs to those drugs that would pose an excessive financial risk to hospitals if they are packaged.

To develop such a system, we will make decisions about each of the four criteria that we discussed in this report. The Commission is certain that an effective system of separately payable drugs should have two features:

- Some drugs should be paid separately because they are not ancillary. These drugs are the purpose for a visit, are high cost, treat a condition, and are usually administered by infusion. Many of these drugs are for cancer treatment, but some, such as infliximab for treatment of autoimmune disorders, treat other conditions. Separate payment for these drugs is consistent with the policy in the APG system.
- Drugs that are ancillary items should show clinical superiority over other drugs to have separately payable status. A clinical superiority requirement is vital. Without one, Medicare could pay separately for a drug no more effective than an existing product, even when the cost of the existing product is reflected in the OPPS payment. This situation would result in a double payment by Medicare.

If we determine that no drugs should be paid separately other than those that are not ancillary, the result would be a system of separately payable drugs that is similar to the EAPG system.

If we determine that some drugs other than the nonancillary drugs should be separately payable, then we would have to determine whether only drugs that are new to the market should be allowed to be separately payable or whether established drugs also should be allowed. Irrespective of that decision, we would also have to make decisions about the two cost-related criteria:

- *Cost per day must exceed a dollar threshold.* It is not clear whether the $130 per day threshold that CMS uses in the program for SPNPT drugs is the appropriate level. Empirical analysis is needed.
- *Cost of the drug relative to the payment rate of the associated service exceeds a threshold.* When a drug is packaged, the difference between the cost of the drug and the amount of the cost that is reflected in the payment rate of the associated service is the loss a hospital faces each time it uses that drug with that service. We would have to determine the point at which that loss in relation to the payment rate of the associated service places excessive risk on hospitals.

In future work, we will perform analyses to determine other criteria for identifying separately payable drugs and determine the parameters for those criteria. ■

Endnotes

1 The formula for the geometric mean differs from the formula for the more common arithmetic mean. The formula for the geometric mean of a sample of N numbers is $(\prod Y_i)^{(1/N)} = (Y_1 * \times Y_2 \times \ldots \times Y_n)^{(1/N)}$. The formula for the arithmetic mean of a sample of N numbers is $(\sum Y_i)/N = (Y_{1+}Y_{2+}\ldots+Y_n)/N$. An important difference between the geometric mean and the arithmetic mean is that outliers (unusually high or unusually low values) have a smaller effect under the geometric mean.

2 The level of program spending and beneficiary cost sharing in 2018—$12.9 billion—was mitigated by a policy that CMS instituted in 2018 that reduces the OPPS payment rate for SPNPT drugs obtained through the 340B Drug Pricing Program from 106 percent of the average sales price (ASP + 6 percent) to ASP – 22.5 percent. We estimate that if the OPPS payment rate for SPNPT drugs had been ASP + 6 percent in 2018, combined program spending and beneficiary cost sharing would have been $14.8 billion in 2018.

3 For 2020, CMS has changed the NTAP criteria for meeting substantial clinical improvement. For products that have received a designation as a breakthrough device from the Food and Drug Administration, CMS does not require the standard clinical improvement criteria. All other items must still meet the standard criteria for clinical improvement.

4 The EAPG system collects separately paid cancer treatment drugs into several categories on the basis of drug cost. All drugs in the same category have the same payment rate. The EAPG system does the same thing for all separately paid noncancer drugs. In contrast to the EAPG system, the OPPS provides a distinct, separate payment rate for each separately paid drug. The EAPG method can be thought of as a technique of consolidated billing.

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CHAPTER 7

Improving Medicare's end-stage renal disease prospective payment system

RECOMMENDATIONS

7-1 The Congress should direct the Secretary to eliminate the end-stage renal disease prospective payment system's transitional drug add-on payment adjustment for new drugs in an existing end-stage renal disease functional category.

COMMISSIONER VOTES: YES 17 • NO 0 • NOT VOTING 0 • ABSENT 0

7-2 The Secretary should replace the current low-volume and rural payment adjustments in the end-stage renal disease prospective payment system with a single adjustment for dialysis facilities that are isolated and consistently have low volume, where low-volume criteria are empirically derived.

COMMISSIONER VOTES: YES 17 • NO 0 • NOT VOTING 0 • ABSENT 0

CHAPTER 7

Improving Medicare's end-stage renal disease prospective payment system

Chapter summary

Since 2011, Medicare has paid dialysis facilities under a prospective payment system (PPS) that is based on an expanded bundle of services that includes end-stage renal disease (ESRD) drugs and biologics (hereafter referred to as "drugs"), clinical laboratory tests, and other items and services that were previously paid separately. Drugs included in the bundle are those that can be classified into 1 of 11 ESRD-related functional drug categories, similar to therapeutic classes of drugs. Medicare pays dialysis facilities a case-mix-adjusted base rate for this bundle of services furnished during a dialysis treatment in the facility or in a patient's home, generally up to three treatments per week. The base payment rate is adjusted for certain patient-level characteristics, including patients' age, body surface area, and body mass. Base payments are also adjusted for certain facility characteristics, with separate adjustments that increase payments for facilities with low treatment volume and for facilities in rural locations. Dialysis facilities may receive separate add-on payments when furnishing certain new drugs. In this chapter, we address issues related to the expanded transitional drug add-on payment adjustment (TDAPA) for new ESRD drugs and the payment adjustments for low-volume facilities and for facilities located in rural areas.

The Protecting Access to Medicare Act of 2014 (PAMA) required CMS to implement a drug designation process for including new injectable and

In this chapter

intravenous products into the ESRD PPS bundled payment. Accordingly, the agency established a process that pays dialysis facilities separately for qualifying products under a TDAPA. The original TDAPA policy for new ESRD drugs that CMS adopted in 2016 applied only to drugs that are *not* in 1 of the 11 ESRD functional categories. As of January 1, 2020, CMS expanded the TDAPA to apply to certain dialysis drugs, including biosimilars, that are in 1 of the 11 ESRD functional categories of drugs included in the ESRD bundle. Under the expanded policy, CMS makes a TDAPA for new ESRD-related injectable and intravenous drugs, unless they are generic equivalents or new dosage forms or formulations of drugs included in an existing ESRD functional category, among others. The process that CMS uses to identify eligible products is based on the pathways that the Food and Drug Administration employs to approve new drugs. The agency pays dialysis facilities the eligible product's average sales price for two years; thereafter, the new product is included in the PPS payment bundle without any increase to the base rate. No products have been paid for under the expanded TDAPA policy in 2020. (Since 2018, CMS pays for calcimimetics under a TDAPA policy that is distinct from the expanded TDAPA policy for new ESRD drugs.)

The Commission has raised concerns about the expanded TDAPA policy, underscoring the importance of maintaining the structure of the ESRD PPS and not creating policies that would unbundle services or encourage high launch prices of new drugs and other technologies (Medicare Payment Advisory Commission 2019a, Medicare Payment Advisory Commission 2018). Further, we have noted that the expanded policy would pay facilities twice for a drug in a functional category by paying separately for the new drug under the TDAPA while also including payment for one or more drugs with a similar purpose or use in the ESRD PPS base rate. The duplicative payment not only is an inappropriate use of Medicare funds but also can create incentives for the excessive provision of ESRD-related products (to the extent clinically possible).

The Commission recommends that the Congress direct the Secretary to eliminate the TDAPA for new drugs that are in an existing ESRD functional category already included in the payment bundle. Doing so would maintain the structure of the ESRD PPS and avoid the introduction of incentives to unbundle services covered under the PPS. In addition, eliminating the TDAPA for these drugs would create pressure for drug manufacturers to constrain the growth of prices for new and existing ESRD drugs. At market entry, such new drugs would be included in the ESRD PPS bundle, with no update to the base payment rate. CMS will need to monitor the alignment of Medicare payments with providers' costs as new products are added to the bundle and diffuse into medical practice. The Commission's annual analysis on payment adequacy, ESRD drug use, and changes in patients' outcomes

can help inform policymakers about the future need for rebasing the ESRD PPS's base payment rate.

The Commission has also raised concerns that neither the low-volume payment adjustment (LVPA) nor the rural adjustment accurately targets facilities that both are critical to beneficiary access and have high costs warranting a payment adjustment (Medicare Payment Advisory Commission 2015, Medicare Payment Advisory Commission 2014). The LVPA, which increases a facility's base rate by 23.9 percent, applies to facilities with fewer than 4,000 total treatments in each of the 3 years before the payment year. For these years, a facility's total treatment volume is equal to the sum of (1) the treatments furnished by the facility in question and (2) the treatments furnished by only those facilities under common ownership that were within five road miles from the facility in question. The rural payment adjustment, which increases a facility's base rate by 0.8 percent, applies to all facilities located in rural areas, regardless of treatment volume or proximity to other dialysis facilities. Consequently, in 2017, about 40 percent of LVPA facilities were located within five miles of the next closest facility, while some 385 facilities that did not receive the LVPA were isolated (and therefore necessary for beneficiary access to care) and incurred substantially higher than average costs per treatment. In addition, in 2017, about half of all rural facilities were high volume, and 30 percent of rural facilities were within five miles of the next closest facility.

The Commission recommends that the Secretary replace the LVPA and rural adjustment with a single payment adjustment—a low-volume and isolated (LVI) adjustment—to better protect isolated, low-volume dialysis facilities that are critical to ensure beneficiary access. Facilities that are low volume and isolated are defined based on both a facility's distance from the nearest facility and its total treatment volume. We found that the facilities that would receive the adjustment would be more appropriately targeted. In 2017, an illustrative LVI policy would have applied to 575 freestanding and hospital-based dialysis facilities, compared with the 336 facilities receiving the current LVPA and the 1,257 facilities receiving the rural adjustment. The LVI policy would not have applied to facilities that furnished a high volume of treatments because their economies of scale generally result in lower costs per treatment, on average, than low-volume facilities. Nor would the LVI policy have applied to facilities near another dialysis facility since such facilities are not the sole providers of dialysis services in their communities and thus are not critical to maintaining access to care. Under this illustrative LVI policy, payments for LVPA-receiving facilities that are also isolated (more than 5 miles from the nearest facility) would remain

roughly the same, while payments would increase for facilities farther than 5 miles from the nearest facility and with between 4,000 and 6,000 treatments annually in the 3 years before the payment year. Payments would be reduced for facilities currently receiving a rural payment adjustment that have larger treatment volumes and for those currently receiving a LVPA that are within five miles of another facility. We intend this recommendation to be budget neutral with respect to current policy. ■

Background

In 2018, nearly 395,000 beneficiaries with end-stage renal disease (ESRD) receiving dialysis were covered under fee-for-service (FFS) Medicare and obtained dialysis from approximately 7,400 dialysis facilities. ESRD is the last stage of chronic kidney disease and is characterized by permanent, irreversible kidney failure. Patients with ESRD include those who are treated with dialysis—a process that removes wastes and fluid from the body—and those who have a functioning kidney transplant. Because of the limited number of kidneys available for transplantation and variation in patients' suitability for transplantation, about 70 percent of ESRD patients undergo maintenance dialysis. In 2018, total Medicare spending for outpatient dialysis services was $12.7 billion.

Since 2011, Medicare has paid dialysis facilities under a prospective payment system (PPS) for an expanded bundle of services that includes ESRD-related drugs and biologics, clinical laboratory tests, and other items and services that were previously paid separately.[1] CMS established 11 ESRD-related functional drug categories, similar to therapeutic classes of drugs, that are included in the bundle. The 11 functional categories are (1) access management, (2) anemia management, (3) bone and mineral metabolism, (4) cellular management, (5) antiemetic, (6) anti-infective, (7) antipruritic, (8) anxiolytic, (9) excess fluid management, (10) fluid and electrolyte management, and (11) pain management. Among the drugs falling into the 11 functional categories are Part B ESRD injectable drugs (such as erythropoietin-stimulating agents (ESAs), iron, and vitamin D analogs) and their oral equivalents, and oral calcimimetics (which were covered under Part D before 2018) and their injectable equivalent. Oral-only dialysis drugs (phosphate binders) are currently paid for under Part D. Statutory provisions delayed the inclusion of oral-only Part D ESRD-related drugs into the Part B payment bundle until 2025.

The unit of payment covered by the PPS rate is a single dialysis treatment. Medicare pays facilities furnishing dialysis treatments in the facility or in a patient's home for up to three treatments per week, unless there is documented medical justification showing that the additional dialysis treatments are reasonable and necessary. Medicare payment for adult dialysis beneficiaries does not vary based on dialysis method (hemodialysis vs. peritoneal dialysis) or site of care (in center vs. a beneficiary's home).[2] For 2020, the base payment rate is $239.33 per treatment.

To calculate the case-mix-adjusted payment rate for a dialysis treatment, the base rate is adjusted to reflect patient-level and facility-level characteristics. Each adjustment is applied as a multiplier to the base rate. All adjustment values are greater than one by design and therefore increase the payment for all dialysis treatments above the base rate (with one exception for body surface area, which can increase, decrease, or have no effect on the base payment rate). Table 7-1 (p. 186) shows the value of patient-level and facility-level adjustments as initially implemented in 2011 and revised by CMS in 2016 (the current set of adjustments).

The labor-related portion (52.3 percent) of the base rate is adjusted for differences in area wages using the inpatient hospital wage index (calculated without regard to geographic reclassification).[3] In addition to the case-mix-adjusted base rate, CMS may pay facilities:

- an outlier payment when a beneficiary's cost per treatment for outlier services exceeds a threshold. Outlier services include drugs, laboratory services, and other items that facilities separately billed before 2011 (under the old payment method).
- an add-on payment for furnishing self-dialysis training to patients beginning home dialysis. CMS pays for up to 15 training sessions for home peritoneal dialysis and 25 sessions for home hemodialysis.
- a transitional drug add-on payment adjustment (TDAPA), as of 2018, for furnishing oral and intravenous calcimimetics, drugs that are indicated for the treatment of secondary hyperparathyroidism in patients on dialysis. (Before 2018, the oral formulation was covered under Part D.) In 2018, Medicare's TDAPA payment was based on each product's average sales price (ASP), and payments equaled $1.2 billion. CMS is continuing the TDAPA for calcimimetics in 2020 because the agency is still in the process of collecting sufficient claims data for a rate-setting analysis, at which point the products will be included in the PPS bundle.
- a TDAPA, as of 2020, for certain new ESRD drugs that are in an existing ESRD functional category or are in a new ESRD functional category. To date, no new drugs (either in an ESRD functional category or not) have qualified for an adjustment.

TABLE 7-1 **ESRD PPS adjustment factors**

Payment adjustment	Value 2011–2015	Value beginning 2016
Age		
18–44	1.171	1.257
45–59	1.013	1.068
60–69	1.000	1.070
70–79	1.011	1.000
80+	1.016	1.109
Body surface area (per 0.1 m^2)	1.020	1.032
Underweight (body mass index < 18.5 kg/m^2)	1.025	1.017
Time since onset of dialysis (<4 months)	1.510	1.327
Acute comorbidities		
Pericarditis	1.114	1.040
Gastrointestinal tract bleeding	1.183	1.082
Bacterial pneumonia	1.135	N/A
Chronic comorbidities		
Hereditary hemolytic/sickle cell anemia	1.072	1.192
Myelodysplastic syndrome	1.099	1.095
Monoclonal gammopathy	1.024	N/A
Facility low-volume status	1.189	1.239
Facility rural location	N/A	1.008

Note: ESRD (end-stage renal disease), PPS (prospective payment system), N/A (not applicable). Payment adjustment factors for adults ages 18 and older. Before 2016, CMS did not use a rural payment adjustment in the ESRD PPS. As of 2016, CMS eliminated the payment adjusters for bacterial pneumonia and monoclonal gammopathy.

Source: Centers for Medicare & Medicaid Services 2015.

Current payment for new ESRD drugs under the ESRD PPS

The Protecting Access to Medicare Act of 2014 (PAMA) required CMS to implement a drug designation process for including new injectable and intravenous products into the ESRD PPS bundled payment. Accordingly, the agency established a process that pays dialysis facilities separately for qualifying new products under a TDAPA, which is summarized in Table 7-2. Generally, CMS makes a TDAPA for new ESRD-related injectable and intravenous drugs, unless they are generic equivalents or new dosage forms or formulations of drugs included in an existing ESRD functional category. Beginning in 2020, the agency lowered the payment for any drug that qualifies for a TDAPA from 106 percent of the drug's ASP to 100 percent of the drug's ASP.

TDAPA policy for new ESRD drugs not in an existing ESRD functional category

To comply with PAMA's mandate for including new ESRD-related injectable and intravenous drugs into the prospective payment bundle, the agency finalized a policy in 2016 that pays a TDAPA for new ESRD-related injectable drugs not in 1 of 11 ESRD-related functional categories of drugs included in the PPS payment bundle. These drugs are eligible for a TDAPA for at least two years, until sufficient rate-setting data are available. When

TABLE 7-2

Summary of the ESRD PPS's TDAPA policy for new injectable drugs and biologics in 2020

	New ESRD-related drugs and biologics that:	
	Are not in an existing ESRD-related functional category	**Are in an existing ESRD-related functional category**
Year the add-on payment policy began	2016 (no products have been eligible for TDAPA to date)	2020 (no products have been eligible for TDAPA to date)
Is "substantial clinical improvement" standard used?	No	No
Payment rate of add-on	ASP*	ASP*
Length of add-on payment period	At least two years (until sufficient rate-setting data are available)	Two years
Is the new drug included in the PPS payment bundle at the end of the add-on payment period?	Yes	Yes
Is the PPS base rate updated at the end of add-on payment period?	Yes	No

Note: ESRD (end-stage renal disease), PPS (prospective payment system), TDAPA (transitional drug add-on payment adjustment), ASP (average sales price).
*In 2016, CMS set payment based on 106 percent of each drug's ASP. As of 2020, CMS sets payment based on 100 percent of each drug's ASP. To date, no drugs have qualified under either TDAPA policy.

Source: MedPAC analysis of final ESRD payment rules for 2016, 2019, and 2020.

the TDAPA period ends, CMS includes the drug in the PPS payment bundle (by adding a new functional category or modifying an existing one) and adjusts the PPS base rate, if appropriate, to reflect changes to the functional categories.[4] To date, no new ESRD-related injectable drug has qualified under this TDAPA policy.

TDAPA policy for new ESRD drugs in an existing ESRD functional category

In the 2019 ESRD PPS final rule, CMS made two important changes to the TDAPA policy that expanded the types of drugs that would be eligible for the add-on payment. First, it expanded the TDAPA to allow add-on payments for all new ESRD injectable products (including generic drugs and biosimilars) that are in an existing ESRD-related functional category and approved by the Food and Drug Administration (FDA) on or after January 1, 2020. Second, CMS extended the TDAPA to allow add-on payments for functional categories of drugs that were, before 2011, paid under the prior ESRD payment system's prospective payment—the composite rate. In other words, the expanded TDAPA policy would make an add-on payment for any new ESRD-related product for two years, even for a new drug with a functional equivalent already included in the payment bundle.[5] After two years, CMS will include the drug in the PPS payment bundle but will make no modifications to the ESRD PPS base payment rate because there would be no changes to the functional categories. Once included in the ESRD PPS payment bundle, new products considered to be composite rate drugs would not be eligible for an outlier payment, but other new drugs would be eligible for outlier payments. According to CMS, the expanded policy is intended "to promote innovation and bring more high-value drugs to market" (Centers for Medicare & Medicaid Services 2018).

Medicare does not apply substantial clinical improvement criteria to determine a drug's eligibility to receive a TDAPA

CMS explicitly elected not to include substantial clinical improvement criteria to determine whether a new dialysis product receives a transitional drug add-on payment adjustment (TDAPA), stating that (1) its policy will provide an opportunity for new drugs to compete with other similar drugs in the market, which could result in lower prices for all drugs, and (2) the effectiveness of drugs can depend on age, gender, race, genetic predisposition, and comorbidities (Centers for Medicare & Medicaid Services 2018). With respect to paying a TDAPA for biosimilars, the agency explained that although biosimilar products do not offer a new treatment method, the agency will pay a TDAPA for these products because their exclusion "would disadvantage this sector of biological products in a space where we are trying to support technological innovation." According to the agency, "While the products [biosimilars] themselves may not be innovative, CMS believes that the technology used to develop the products is sufficiently new and innovative to warrant a TDAPA payment at this time" (Centers for Medicare & Medicaid Services 2019). ■

In response to concerns from stakeholders about the broad nature of the 2019 TDAPA policy expansion, CMS refined the TDAPA eligibility criteria in the rule-making process for the 2020 ESRD PPS, excluding drugs in an ESRD functional category from receiving an add-on payment if the agency considers them to be "not truly innovative," based on FDA approval pathways (Centers for Medicare & Medicaid Services 2019). Under CMS's finalized policy, the following new ESRD drugs in an existing functional category are not eligible for a TDAPA:

- generic drugs (i.e., drugs that the FDA approves under section 505(j) of the Federal Food, Drug, and Cosmetic Act) and
- new drugs approved for a new dosage form (e.g., pill size, time-release forms, chewable or effervescent pills); new drugs approved for a new formulation (e.g., new inactive ingredient); new approved drugs that were previously marketed without a new drug application (NDA); new approved drugs that changed from prescription to over the counter, among others. CMS would identify these drugs using the NDA classification code assigned by the FDA.[6]

Under CMS's finalized policy, new products in an existing ESRD functional category that are eligible for the TDAPA include products that contain a new molecular entity, a new active ingredient, or a new combination of drugs involving two or more active ingredients (for which one ingredient is a new molecular entity). As described in the text box on TDAPA eligibility criteria, in both the 2019 and 2020 rule-making process, CMS opted not to apply substantial clinical improvement criteria to determine a drug's eligibility to receive a TDAPA.

Eliminating the TDAPA for new drugs in an existing ESRD functional category

Under current policy, for new ESRD drugs in an existing functional category, CMS does not reduce either the TDAPA payment or the base rate even though the cost of providing all drugs in a given functional category is included in the base rate. CMS elected not to account for the duplicative payment when expanding the TDAPA policy in 2019 and 2020, stating that the policy is temporary and not duplicative because, at the end of the two-year period, there is no additional money added to the base rate for those drugs in an existing functional category.

However, during the two-year period, Medicare effectively pays dialysis facilities twice for a drug in an existing functional category by paying separately for the new drug under the TDAPA while also including payment for

one or more drugs with a similar purpose or use in the ESRD PPS base rate. The TDAPA's ASP-based payment, which Medicare pays according to the number of units administered, creates incentives for potential overuse of drugs. Providers realize greater profits from larger doses than small doses of the TDAPA product (as long as Medicare's payment rate exceeds providers' costs). In addition, ASP-based payments provide no incentive for drug manufacturers to constrain the prices of new ESRD drugs. Further, by paying separately for new drugs in an existing functional category, Medicare misses an opportunity to encourage price competition among therapeutically similar drugs in the payment bundle.

Eliminating the TDAPA for new drugs in an existing ESRD functional category already included in the payment bundle would preserve the structure of the ESRD PPS by not unbundling services already covered under the PPS, create pressure for drug manufacturers to constrain the prices for new and existing ESRD drugs, and maximize price competition among therapeutically similar drugs in the payment bundle (Medicare Payment Advisory Commission 2019a, Medicare Payment Advisory Commission 2018). (The TDAPA for drugs not in an existing ESRD functional category would remain unchanged.)

By eliminating the TDAPA, no additional payments would be made for new drugs in an existing functional category at market entry because payment is already included in the payment bundle. There would be no concurrent update to the base rate after a new drug in an existing ESRD functional category is introduced and included in the PPS payment bundle. This policy would be consistent with the TDAPA policy that CMS implemented between 2016 and 2019.

As new products are added to the bundle and diffused into medical practice, there may be a need for rebasing to keep Medicare payments aligned with providers' costs. For example, the Congress mandated that the Secretary rebase the ESRD PPS base payment rate in 2014 to account for the decline in the use of dialysis drugs covered under the bundle.[7] The Commission's annual payment adequacy analysis can help inform policymakers about the alignment of Medicare's payments to providers' costs. Our payment adequacy analysis also tracks dialysis drug use and changes in patients' outcomes over time.

Some stakeholders have raised concerns that access to new drugs in an ESRD functional category would be impeded without a TDAPA and that not updating the base rate to account for new drugs would dampen drug manufacturers' investment in developing new ESRD drugs. However, under the ESRD PPS, beneficiaries appear to have good access to new products that are in an ESRD functional category. For example, in 2015, epoetin beta, an erythropoietin-stimulating biologic, was introduced to the U.S. market. CMS included the biologic in the ESRD PPS payment bundle; facilities did not receive a TDAPA for this product. Nevertheless, by the end of 2015, nearly one-quarter of dialysis beneficiaries had received this new biologic. One of the two large dialysis organizations (Fresenius) switched about 70 percent of its patients to the new biologic within one year after the product's market entry. Thus, including the new biologic in the payment bundle (without any TDAPA) resulted in increased competition and efficiencies. The Commission's analysis of this company's cost reports submitted to CMS showed that its ESA cost per treatment declined between 2015 and 2016. Further, there is no indication that beneficiary quality of care was affected by the treatment change.

There is concern that use of new ESRD drugs may be constrained by long-term contracts that some dialysis organizations have with drug manufacturers.[8] However, under the ESRD PPS, the use of anemia and vitamin D drugs has shifted over time (Medicare Payment Advisory Commission 2017). Although some dialysis organizations have long-term contracts with particular drug vendors, the Medicare program should not expect the existence of such contracts to be an obstacle to beneficiaries receiving new treatments if those are better for the patient.

Some stakeholders have also asserted that it is not appropriate to assume that the base rate is sufficient to support new drugs that represent a clinical improvement. However, in the Commission's view, paying a TDAPA for new drugs in an existing ESRD functional category—irrespective of whether they meet a substantial clinical improvement standard—would undermine the competitive forces within the PPS payment bundle because the add-on would fail to create pressure on drug manufacturers to constrain prices for new and existing ESRD drugs.

An important goal of the ESRD PPS is to give dialysis facilities an incentive to provide ESRD-related items and services as efficiently as possible. This goal is best achieved by relying on the ESRD bundle to the greatest extent possible when determining payment amounts. Bundled payment encourages judicious consideration of

the items and services provided to patients. Paying the TDAPA for two years for new ESRD drugs in an existing functional category is duplicative of the payment already made as part of the ESRD bundle. Instead, including all ESRD drugs in an existing functional category (and thus with a similar function) in the bundle would foster competition for these products and generates pressure to constrain prices.

RECOMMENDATION 7-1

The Congress should direct the Secretary to eliminate the end-stage renal disease prospective payment system's transitional drug add-on payment adjustment for new drugs in an existing end-stage renal disease functional category.

RATIONALE 7-1

This recommendation would eliminate the TDAPA for new ESRD drugs included in an existing ESRD functional category, which is consistent with CMS's policy between 2016 and 2019. The recommendation would maintain the structure of the ESRD PPS by continuing to bundle services covered under the PPS and would reduce incentives for high launch prices of new drugs. This recommendation would also prevent duplicative payments for new drugs for which payment is already included in the ESRD bundle.

IMPLICATIONS 7-1

Spending

- This recommendation is estimated to decrease program spending by $250 million to $750 million over one year and by $1 billion to $5 billion over five years relative to current policy.

Beneficiaries and providers

- We do not anticipate any negative effects on beneficiary access to care. This recommendation would generate savings for beneficiaries through lower cost sharing and would reduce future payments to dialysis facilities without affecting dialysis facilities' willingness and ability to care for beneficiaries.

Current payment for low-volume and rural dialysis facilities

The ESRD PPS includes a payment adjustment for facilities with low treatment volume and a separate adjustment for facilities located in rural locations. Facilities with low treatment volume receive a significant upward payment adjustment regardless of their proximity to other providers; some facilities receive a low-volume adjustment even if they are located in close proximity to another dialysis provider and are thus not critical to maintaining access to care. At the same time, Medicare makes an adjustment for rural facilities regardless of the number of treatments they provide. Yet dialysis treatment volume is highly correlated with dialysis facilities' costs. The greater the facility's service volume, the lower its costs per treatment. Some rural facilities thus receive an upward adjustment to their payments even when they realize significant economies of scale. Indeed, after controlling for treatment volume, the difference in the cost per treatment between urban and rural facilities narrows considerably.

Current payment adjustment for low-volume facilities

The Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) required the ESRD PPS to include "a payment adjustment that reflects the extent to which costs incurred by low-volume facilities (as defined by the Secretary) in furnishing renal dialysis services exceed the costs incurred by other facilities in furnishing such services." CMS used regression analyses to empirically determine the magnitude of the adjustment.

Between 2011 and 2015, per regulation, CMS defined a low-volume facility as one that provided fewer than 4,000 total treatments in each of the three years before the payment year. For these years, a facility's total treatment volume was equal to the sum of (1) the treatments furnished by the facility in question and (2) the treatments furnished by other facilities under common ownership that were within 25 road miles of the facility in question. However, the agency exempted facilities that were certified for Medicare participation as of December 31, 2010, from the distance requirement between the facilities that received the low-volume payment adjustment (LVPA) and the next closest facility (the so-called "grandfather" provision).

In our March 2014 report, we stated that only the low-volume ESRD facilities necessary to maintain access—those located in isolated areas—should receive enhanced payment, and recommended that the Congress direct the Secretary to redesign the LVPA to consider a facility's distance to the nearest facility regardless of ownership

CMS requires facilities to attest to their qualification for the low-volume payment adjustment

CMS requires facilities to attest that they qualify for the low-volume payment adjustment (LVPA), including the total treatment volume in the three preceding years.[9] At the time of attestation, cost report data is available only for the first two of the three years preceding the payment year. Attestation is necessary because some of the information the Medicare administrative contractors (MACs) need to assess a facility's eligibility—in particular a dialysis facility's cost reports for the year immediately preceding the payment year—may be unavailable to the MACs until several months after the payment year begins.[10]

Only after the dialysis facility has submitted its attestation and its designated MAC has verified that the facility meets the eligibility criteria will a facility begin to receive the LVPA. According to the Government Accountability Office (GAO), in cases where the MACs cannot make a final eligibility determination at the beginning of the payment year, they conditionally approve LVPA eligibility. After the necessary information becomes available, the MACs are required to reassess the dialysis facility's eligibility for the LVPA (Government Accountability Office 2013). If a MAC determines that a facility receiving the LVPA was ineligible, the MAC is expected to recoup all payments to that facility made under the LVPA within six months of that determination.

Determining LVPA eligibility is a passive process for CMS, in which dialysis facility attestations are reviewed by the MACs. Dialysis facilities must assess LVPA eligibility on their own and submit an attestation before CMS or one of the MACs considers a facility's eligibility for the LVPA. Both GAO and the Commission's analysis found that eligible facilities did not receive the LVPA. Under the original LVPA policy (that was in place between 2011 and 2015), GAO determined that 79 eligible facilities in 2011 did not receive the LVPA for any treatments. Under the current LVPA policy (in place as of 2016), the Commission found more than 100 facilities in 2017 that appeared to be eligible but did not receive the LVPA (based on publicly available information on each facility's ownership that is reported in CMS's cost reports and Dialysis Facility Compare file). ■

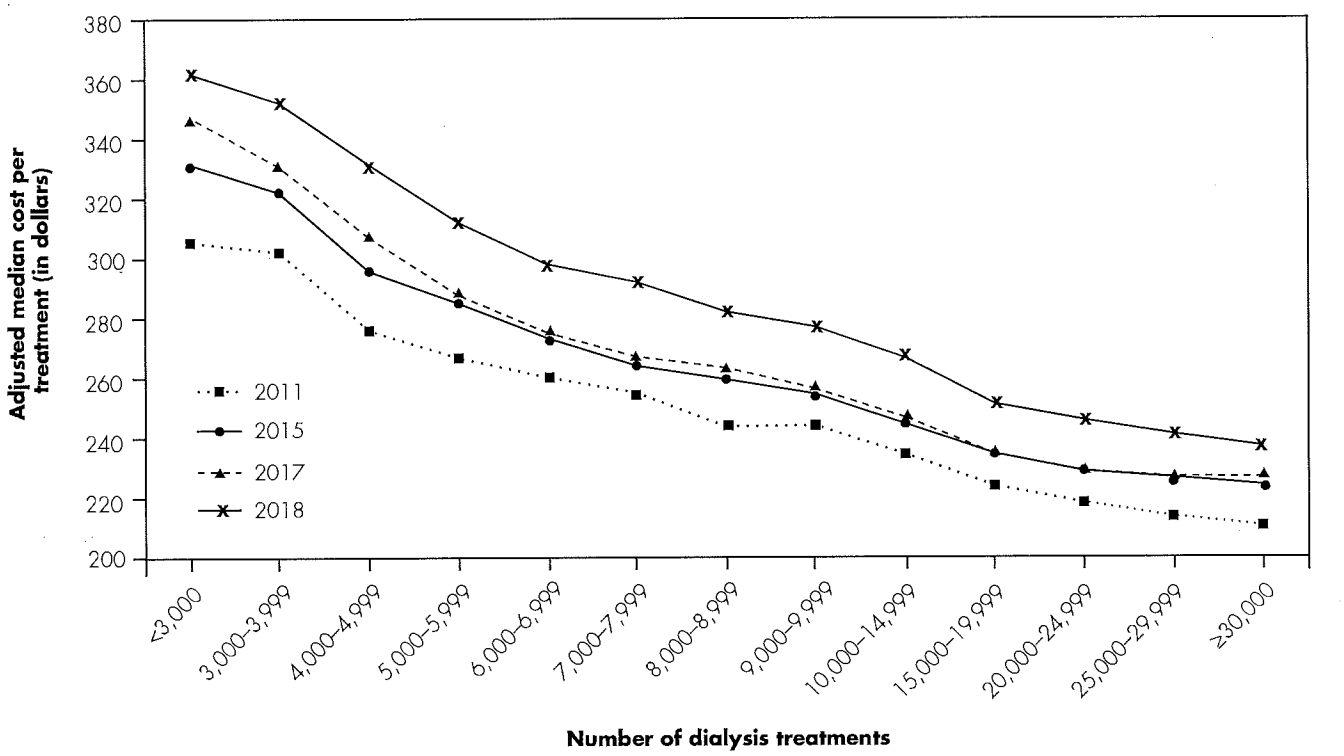
(Medicare Payment Advisory Commission 2014). In 2016, CMS revised the LVPA definition by:

- decreasing the geographic proximity criterion from 25 miles to 5 miles. For the purposes of determining eligibility, a facility's total treatment volume is equal to the sum of (1) the treatments furnished by the facility in question and (2) the treatments furnished by other facilities under common ownership that are within five road miles of the facility in question.
- applying the five-mile distance requirement to all facilities regardless of when a facility was certified for Medicare participation. CMS no longer exempts facilities that were certified before 2011 from the distance requirement.

The 2016 changes did not alter the volume threshold; a low-volume facility is still defined as one that provides fewer than 4,000 treatments (Medicare and non-Medicare) in each of the 3 years before the payment year and has not opened, closed, or received a new provider number due to a change in ownership during the 3-year period.[11] As described in the text box on qualification for the LVPA, to establish eligibility, a facility must provide an attestation statement to its designated Medicare administrative contractor (MAC), which is responsible for verifying that the facility has met the eligibility criteria.

Because eligibility for the LVPA requires fewer than 4,000 treatments in each of the 3 years before the payment year, a facility could have an incentive to avoid providing 4,000 treatments or more in a given year

FIGURE 7-1 **Higher volume facilities have lower cost per treatment**



Note: Cost per treatment is adjusted to remove differences in the cost of labor. Dialysis treatments include those paid for by all sources (not just Medicare-paid treatments).

Source: MedPAC analysis of cost reports submitted by freestanding dialysis facilities to CMS and the end-stage renal disease wage index files.

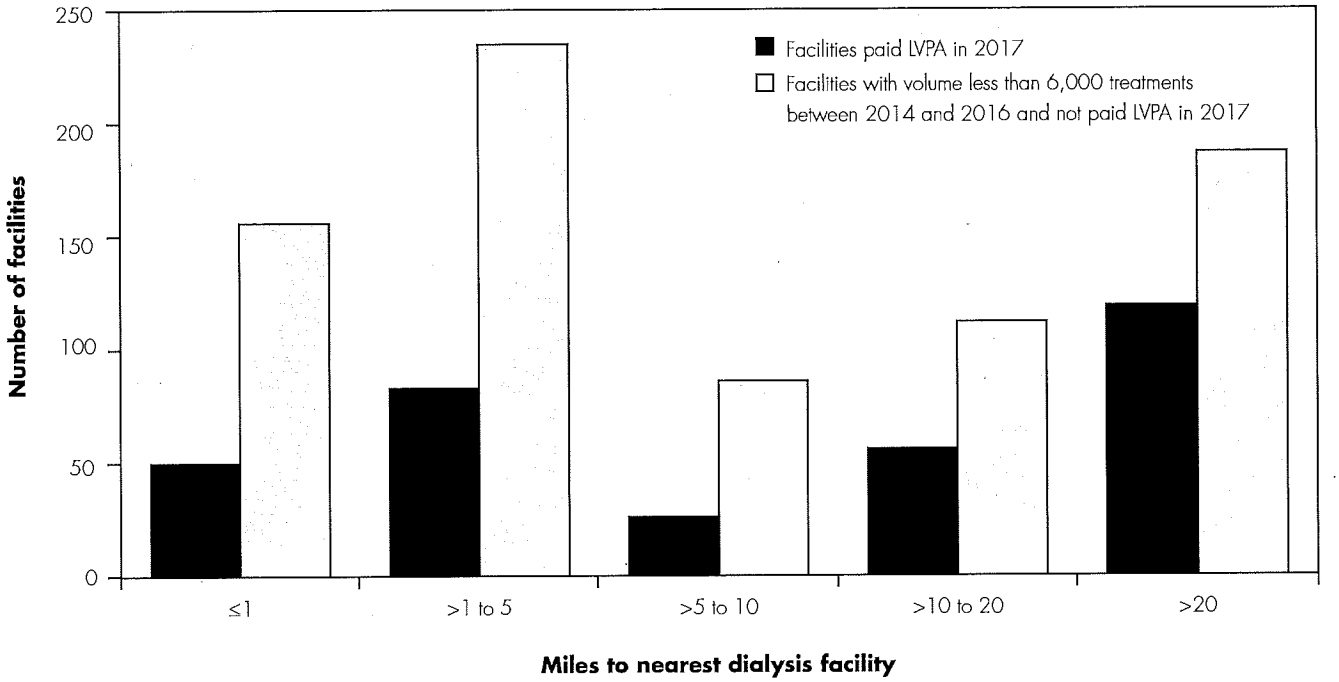
(Government Accountability Office 2013). In addition, the 4,000-treatment cut-off for LVPA eligibility leaves many facilities with comparatively low treatment volume without an adjustment for their higher average costs per treatment.[12] As shown in Figure 7-1, facilities providing 4,000 to 5,999 treatments per year also have relatively high average treatment costs, although not as high as facilities furnishing under 4,000 treatments per year.

LVPA freestanding facilities incur substantially higher costs per treatment compared with all freestanding facilities.[13] In 2017, the adjusted cost per treatment of LVPA freestanding facilities was about $320 per treatment, 28 percent greater than the adjusted cost per treatment of the other freestanding facilities. Among LVPA facilities, costs did not substantially vary based on their proximity to the nearest facility. For example, LVPA freestanding facilities located within five miles of the next facility incurred a median adjusted cost of $324 per treatment, while LVPA facilities located more than five miles from the next facility incurred an adjusted cost of $318 per treatment.

In 2017, 270 freestanding and 66 hospital-based facilities received the LVPA, which increased their base payment rate by 23.9 percent. Figure 7-2 shows that some facilities receiving the LVPA were located near other facilities, suggesting that they may not have been essential for ensuring access to care. For example, in 2017, among facilities receiving the LVPA, 40 percent were located within five miles of the next closest facility and 15 percent were located within one mile of the next closest facility (data not shown). These proximities reflect the LVPA's design, which, for the purposes of determining a facility's

FIGURE 7-2

Current design of LVPA includes facilities in close proximity to another facility and excludes some isolated low-volume facilities



Note: LVPA (low-volume payment adjustment).

Source: MedPAC analysis of 2017 claims and 2017 cost reports submitted by dialysis facilities to CMS, Dialysis Facility Survey, and the Dialysis Facility Compare.

total treatments, excludes the treatments from facilities within five miles of the facility in question that are not under the same corporate ownership from the facility in question. In addition, Figure 7-2 shows that the current design of the LVPA does not include roughly 385 facilities that furnished fewer than 6,000 total treatments and were located more than 5 miles from the nearest facility.

Compared with all dialysis facilities, LVPA facilities in 2017 were more likely to be hospital based, rural, and not associated with the two largest dialysis organizations; each of these facility types was more likely to be farther from the next closest facility than its counterparts (freestanding, urban, and affiliated with the two largest dialysis organizations, respectively) (Table 7-3, p. 194). We found similar results when examining the proximity of low-volume facilities to other facilities in 2011 and 2012 (Medicare Payment Advisory Commission 2014).

Current payment adjustment for rural location

MIPPA gave the Secretary the authority to include (but did not require) a payment adjustment for facilities located in rural areas. In the rule-making process that implemented the ESRD PPS in 2011, the agency explained that a rural adjustment was not necessary because the impact of the new ESRD PPS was lower for rural facilities than urban facilities (and other subgroups) (Centers for Medicare & Medicaid Services 2015). Thus, from 2011 through 2015, the ESRD PPS did not include a rural payment adjustment.

Starting in 2016, CMS established a rural payment adjustment that increased the ESRD PPS base rate by 0.8 percent for facilities in rural areas. According to CMS, this change was adopted to address concerns from stakeholders about low-to-negative Medicare margins for rural facilities

TABLE 7-3

Dialysis facilities receiving the LVPA were more likely to be hospital based, located in rural areas, and not associated with the two largest dialysis organizations, 2017

	Facilities receiving the LVPA			All facilities		
	Percent of all LVPA facilities	Percent within 5 miles of nearest facility	Median miles to nearest facility	Percent of all facilities	Percent within 5 miles of nearest facility	Median miles to nearest facility
All facilities	100%	40%	11.6	100%	73%	2.2
Freestanding	81	45	7.5	95	74	2.2
Hospital based	19	22	27.0	5	63	2.3
Urban	49	60	3.4	82	82	1.9
Rural	51	20	23.9	18	31	18.7
LDO associated	62	45	7.2	73	72	2.3
Non LDO	38	31	19.9	27	11	1.9

Note: LVPA (low-volume payment adjustment), LDO (large dialysis organization). The number of facilities receiving the LVPA was 336; the number of all facilities was 7,089.

Source: MedPAC analysis of claims and cost reports submitted by dialysis facilities to CMS and the Dialysis Facility Compare file.

(Centers for Medicare & Medicaid Services 2015). For purposes of the rural payment adjustment, a rural area is defined as any area outside of an urban area.[14] The rural adjustment does not impose a distance requirement between a facility that receives this adjustment and the next closest facility and does not consider a rural facility's treatment volume. In 2017, 1,257 freestanding and hospital-based facilities were located in rural areas and thus received the 0.8 percent rural adjustment.

TABLE 7-4

Adjusted cost per treatment is similar between urban and rural facilities with comparable treatment volume, 2017

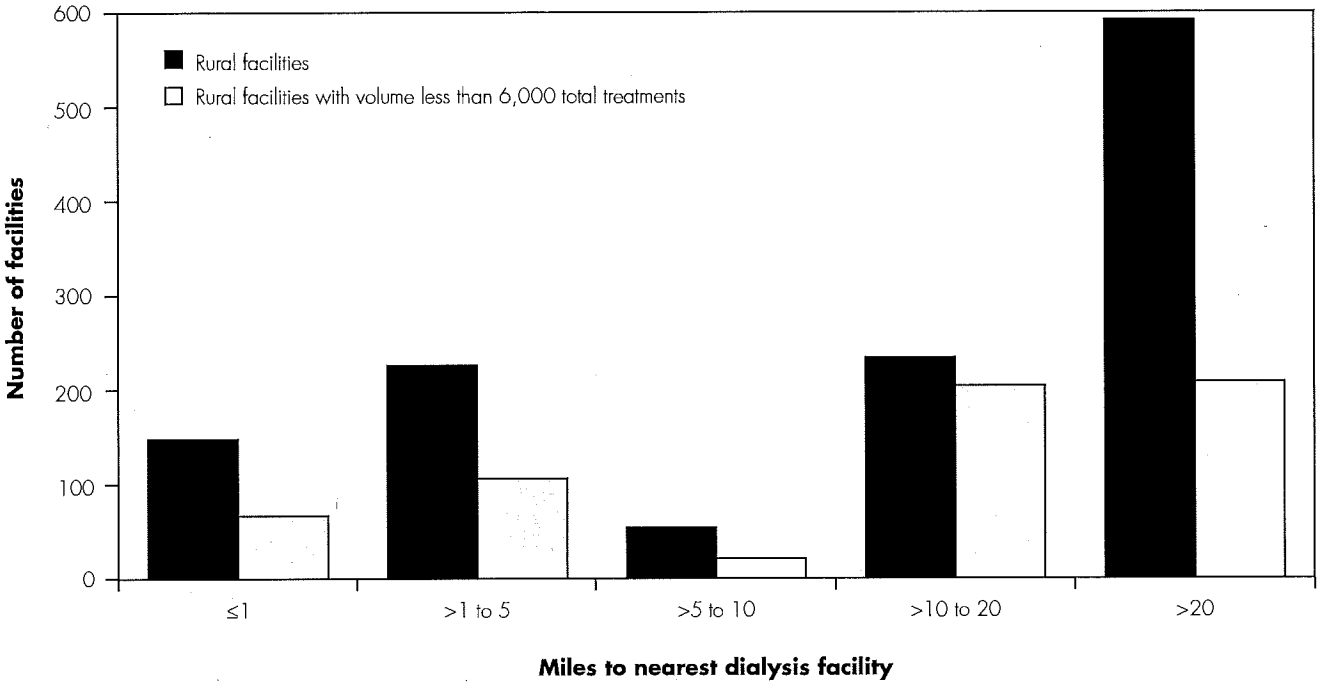
Annual number of dialysis treatments	Urban	Rural	Ratio of adjusted cost per treatment: urban to rural facilities
<4,000	$337	$337	1.00
4,000–4,999	310	309	1.00
5,000–5,999	296	289	1.02
6,000–6,999	282	280	1.01
7,000–7,999	271	273	0.99
8,000–8,999	263	270	0.98
9,000–9,999	259	256	1.01
10,000–14,999	248	256	0.97
≥15,000	232	240	0.97

Note: Cast per treatment is adjusted to remove differences in the cost of labor. "Dialysis treatments" includes those paid for by all sources (not just Medicare-paid treatments). Analysis is based on freestanding dialysis facilities.

Source: MedPAC analysis of 2017 cost reports submitted by freestanding dialysis facilities to CMS.

FIGURE 7-3

Current design of rural payment adjustment factor includes facilities in close proximity to another facility and facilities that are not low volume



Source: MedPAC analysis of 2017 claims and 2017 cost reports submitted by dialysis facilities to CMS, the Dialysis Facility Survey, and the Dialysis Facility Compare file.

In our comment letter on CMS's proposal to introduce the separate rural adjustment in 2016, the Commission urged the agency to design a single payment adjustment that targets low-volume isolated providers instead of two separate adjustments for low volume and rural location (Medicare Payment Advisory Commission 2015). The Commission's analyses have found differences overall in the adjusted cost per treatment for rural and urban facilities (about $270 per treatment versus nearly $250 per treatment, respectively, in 2017); however, those differences generally are explained by differences between rural and urban facilities in total treatment volume. As shown in Table 7-4, the adjusted cost per treatment is roughly equivalent in rural and urban facilities with similar treatment volume. The 2017 aggregate Medicare margin follows a similar trend: Urban facilities had higher margins than rural facilities (1.3 percent versus –5.1 percent). However, after controlling for treatment volume, the gap between urban and rural facilities narrows (data not shown).

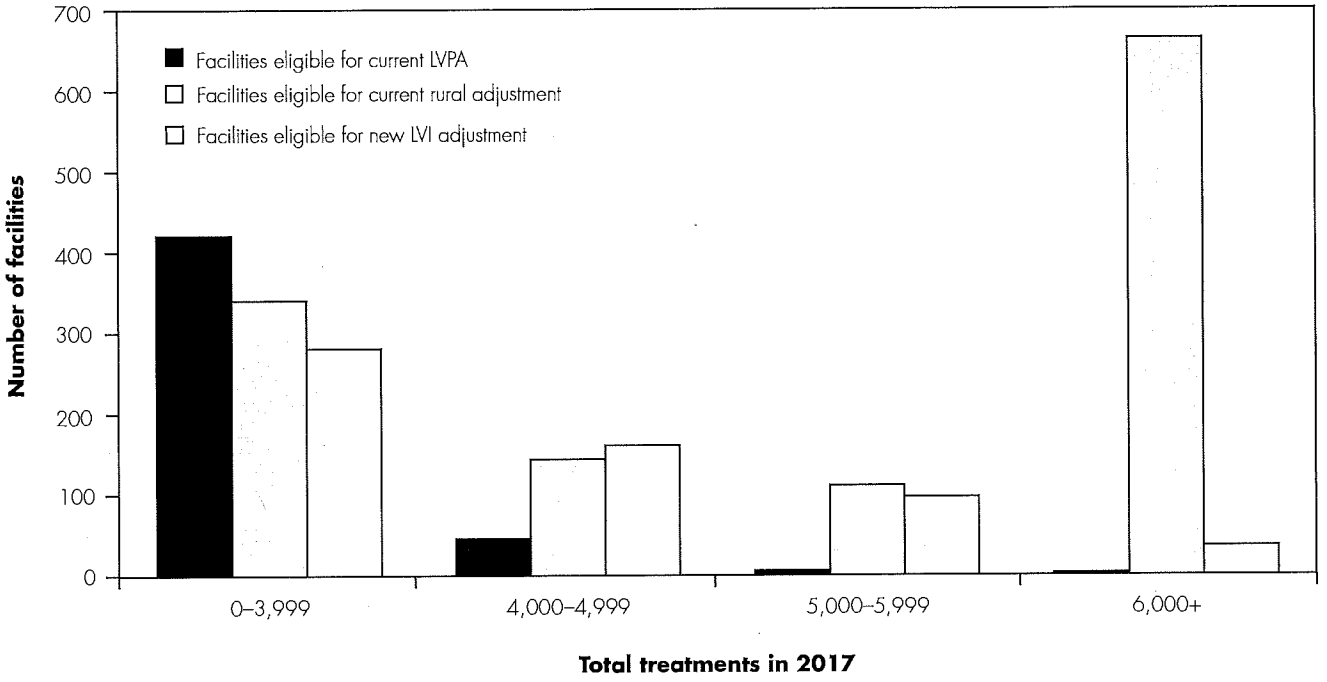
In 2017, high-volume rural facilities (which represent about half of all rural facilities) received the 0.8 percent rural adjustment despite having adjusted costs per treatment that were similar to their high-volume urban counterparts (Table 7-4). In addition, 30 percent of rural facilities were within five miles of the next closest facility (Figure 7-3).

Improving the adequacy of payments for low-volume and isolated facilities

The design of the LVPA and rural payment adjustment are not consistent with the Commission's principles guiding special payments to rural providers (see text box on

FIGURE 7–4

A new LVI adjustment would better target payments to low-volume, isolated dialysis facilities



Note: LVI (low-volume and isolated), LVPA (low-volume payment adjustment). Analysis includes freestanding and hospital-based facilities. Eligibility for the LVPA and the LVI adjustment is based on total treatment volume between 2014 and 2016, the three years before the 2017 payment year in question. In 2017, some LVPA-eligible facilities provided more than 4,000 treatments, and some LVI-eligible facilities provided more than 6,000 treatments.

Source: MedPAC analysis of claims submitted by freestanding and hospital-based dialysis facilities and cost reports submitted by freestanding dialysis facilities to CMS, the ESRD Facility Survey, and the Dialysis Facility Compare file.

evaluating rural payments). The LVPA does not ensure that only isolated facilities receive the payment adjustment. For example, two facilities not under common ownership could be located in close proximity (e.g., within five miles of one another) and receive the 23.9 percent LVPA to their base rate. Further, there is no distance criterion or volume criterion required for a rural facility to receive the 0.8 percent increase to its base payment rate.

Consistent with the Commission's principles, an adjustment that serves to preserve access to dialysis should focus on isolated *and* low-volume facilities. Neither the LVPA, which increases payment for facilities that are located within five miles of another facility, nor the rural adjustment, which increases payment for high-volume rural facilities, ensures access to dialysis care or spends program funds wisely.

In addition, isolated dialysis facilities, which we define as facilities located more than five miles from the next facility, vary in the number of treatments provided such that isolated facilities exist almost uniformly across all categories of facility treatment volume. For example, in 2017, nearly 30 percent of freestanding and hospital-based dialysis facilities located more than 5 miles from the next facility furnished more than 10,000 treatments.

A single payment adjustment that considers both a facility's distance to the nearest facility and its treatment volume would eliminate extra payments to low-volume facilities in close proximity to another facility and to high-volume rural facilities and instead would target extra payments to low-volume and isolated facilities. A combined low-volume and isolated (LVI) adjustment would require the facility to be isolated and to have a low treatment volume. For example, CMS could use a distance

Guiding principles to evaluate rural special payments

Under the prospective payment system (PPS) for end-stage renal disease (ESRD), low-volume and rural adjustments are not consistent with the Commission's principles regarding Medicare payment policy for rural providers, nor with expectations regarding rural beneficiaries' access to care and rural providers' quality of care (Medicare Payment Advisory Commission 2012). The Commission stated the following principles in our June 2012 report to the Congress:

- Payments should be targeted toward low-volume, isolated providers—that is, providers that have low patient volume and are at a distance from other providers. Distance is required because supporting two neighboring providers that both struggle with low volume can discourage mergers that could lead to lower cost and higher quality care.
- The magnitude of special rural payment adjustments should be empirically justified—that is, the payments should increase to the extent that factors beyond the providers' control increase their costs.
- Rural payment adjustments should be designed in ways that encourage cost control on the part of providers. Fixed add-on payments generally provide a greater incentive for cost control than cost-based payments. ■

of five miles to the nearest facility, the mileage threshold used for the LVPA. (Policymakers could consider using a different mileage threshold as long as it did not affect beneficiaries' access to care.) At the same time, to improve on the current cliff effect exhibited by the LVPA (which gives facilities an incentive to limit services to avoid reaching the 4,000-treatment threshold), CMS could apply the low-volume criterion using a few approaches. One method is to use a continuous function to determine the adjustment size. Using another method, the Commission modeled a categorical approach with three levels of low volume. Either approach would reduce the all-or-nothing application of the LVPA and better match the higher cost per treatment for facilities with relatively low volume. We created the following levels of low volume for three mutually exclusive categories:

- ***Category 1:*** facilities with fewer than 4,000 treatments in each of the 3 years preceding the payment year;
- ***Category 2:*** facilities that had fewer than 5,000 treatments in each of the preceding 3 years (excluding Category 1); and
- ***Category 3:*** facilities that had fewer than 6,000 treatments in each of the preceding 3 years (excluding Categories 1 and 2).

Using 2017 data, Figure 7-4 shows how the illustrative LVI adjustment criteria contrast with the current LVPA and rural adjustment criteria by comparing the number of freestanding and hospital-based facilities eligible for either the LVPA or the rural adjustment with the number of facilities eligible for the LVI adjustment.[15]

Overall, in 2017, 575 facilities would have been eligible to receive the LVI adjustment, compared with 477 facilities eligible for the LVPA and 1,257 facilities eligible for the rural adjustment. Roughly half of facilities eligible for the LVPA and one-quarter of facilities eligible for the rural adjustment would receive the LVI adjustment. Figure 7-4 shows that the expanded categories under the LVI adjustment increase the number of isolated facilities providing between 4,000 and 5,999 treatments that would receive a low-volume adjustment. As seen earlier in Figure 7-1 (p. 192), facilities with treatment volumes between 4,000 and 5,999 also had relatively high cost per treatment.

Table 7-5 (p. 198) shows the number of eligible facilities (freestanding and hospital based) and the median adjusted cost per treatment (based only on freestanding facilities with cost report data) for each of the three LVI categories. Although the size of the LVI category adjustments would be empirically estimated, the median costs demonstrate

TABLE 7-5 Facilities eligible for LVI adjustment have higher costs than all other isolated facilities

	Number of dialysis facilities	Median adjusted cost per treatment
LVI Category 1	255	$320
LVI Category 2	188	304
LVI Category 3	132	278
Reference group: All isolated facilities not receiving an LVI payment adjustment	1,899	250

Note: LVI (low-volume and isolated). LVI Category 1 comprises facilities with fewer than 4,000 treatments in each of the 3 years preceding the payment year. LVI Category 2 comprises facilities that had fewer than 5,000 treatments in each of the preceding 3 years (excluding LVI Category 1 facilities). LVI Category 3 comprises facilities that had fewer than 6,000 treatments in each of the preceding 3 years (excluding LVI Category 1 and LVI Category 2 facilities). Median cost per treatment is based only on freestanding facilities with cost report data and has been adjusted to account for local wage variation.

Source: MedPAC analysis of claims and cost reports submitted by dialysis facilities to CMS.

that the expanded low-volume categories have higher costs than other isolated facilities.

Effect of a low-volume and isolated adjustment on Medicare payments to dialysis facilities

To assess the effect of replacing the current low-volume and rural location adjustments with a single low-volume and isolated adjustment, we used a regression method based on a model previously developed by CMS to explain variation in treatment costs. Using a single facility–level regression model, we assessed the effect of substituting a single payment adjustment—the LVI adjustment—in place of the two adjustments for low volume and rural location that the ESRD PPS currently uses.

Model specification

Our single facility–level regression model uses freestanding dialysis facilities' cost reports submitted to CMS, with the dependent variable equal to a facility's 2017 average cost per treatment, which captures the cost of all services included in the PPS payment bundle, including drugs and laboratory services that were separately billable under the prior payment system. We estimated coefficients for the payment adjustment factors currently included in the ESRD PPS.

We chose a single facility–level regression approach instead of CMS's two-regression approach out of concerns that multiplying coefficients from the facility-level and patient-level regressions (with different bases) could diminish the accuracy of the combined coefficients (Medicare Payment Advisory Commission 2015). The text box outlines our concerns with CMS's two-regression approach.

Our regression model includes freestanding facilities with cost data for 2017 (roughly 400 hospital-based facilities are excluded due to concerns about data validity).[16] To improve the accuracy of regression results, we excluded facilities with outlier values for average cost per treatment (i.e., defined as having logged average treatment cost outside of two standard deviations from the mean). We include the same control variables (i.e., facility size, ownership type, and home dialysis training) as the ESRD PPS-estimating regression, with a few minor differences in definition (i.e., we differentiate between facilities providing 10,000 to 15,000 treatments and more than 15,000 treatments, and we collapsed independent and unknown ownership types). We include the same patient-level variables—age, body mass index, body surface area, comorbid conditions, and time since the onset of ESRD. We specify each set of these variables using the percent of treatment in each category.

The Commission's model findings

As shown in Table 7-6 (p. 200), the current ESRD PPS adjustment values are 1.239 for the LVPA and 1.008 for rural location. (Payment adjustment values are applied

CMS's model specification may not accurately estimate payment adjustment factors

For the end-stage renal disease (ESRD) prospective payment system (PPS), CMS estimated the payment adjustment factors using a two-equation regression methodology. The agency conducted one regression at the facility level and used cost report data to calculate each facility's average treatment cost for the composite rate set of services, adjusted for differences in wages.[17] CMS conducted the second regression at the patient level and used Medicare claims to calculate the average Medicare-allowable per patient payment amount for items and services that formerly were separately billable. Together, the composite rate services and former separately billable services make up the current ESRD bundle.

Each regression includes the same set of control variables and payment adjustment variables shown in Table 7-1 (p. 186) and estimates a coefficient for each payment adjustment variable.[18] To combine the coefficients from the two regressions, for each adjustment, the coefficient from the composite rate model is multiplied by the share of composite rate service spending, and the coefficient from the former separately billable model is multiplied by the share of former separately billable service spending. The weighted coefficients from each regression are multiplied to derive the final coefficient.

Multiplying coefficients from the facility-level and patient-level regressions (with different bases) can diminish the accuracy of the combined coefficients. Through various re-estimations of the payment adjustment amounts, the empirically determined lowest cost reference population for the age category variables has shifted from ages 45 to 59 in the proposed rule for the 2011 PPS to ages 60 to 69 in the final rule for the 2011 PPS and to ages 70 to 79 in the final rule for the 2016 PPS (Table 7-1, p. 186). We would expect the relative cost of dialysis treatment across age categories to remain roughly stable over time and are concerned that such shifts indicate that the estimated factors are highly sensitive to the model's specification and that the model lacks robustness. The two-equation approach might contribute to the instability of these results.

The Commission advised CMS to develop payment adjustment factors using a single-equation methodology that accounts for variation in the cost of providing the full PPS payment bundle (Medicare Payment Advisory Commission 2015). Given the availability since 2011 of cost data for the full PPS payment bundle, it is no longer necessary to use pre-2011 service categories when developing the adjustment factors. The distribution of average treatment cost across facilities is quite likely to be different from the distribution of payments for separately billable services across patients, and combining the two factors estimated on unrelated distributions may not accurately reflect cost variation for the payment unit, a dialysis treatment. ■

as multipliers to the ESRD PPS base rate; that is, a 1.239 adjustment value would increase the base rate by 23.9 percent.) The Commission's regression analysis estimated payment adjustment values of 1.319 for the LVPA and 1.010 for rural location.[19]

Differences between our results and the current ESRD PPS adjustment values could be due to using different years of data or to differences in the regression specification. As described in the text box on model specifications, CMS used a two-equation regression methodology to derive the ESRD PPS payment adjustments:

- a facility-level regression model that used 2012 and 2013 cost reports submitted by dialysis facilities to CMS, with the dependent variable equal to the average cost per treatment for composite rate services.
- a patient-level regression model that used 2012 and 2013 dialysis facility claims, with the dependent

TABLE 7-6

LVPA and rural location adjustment values in the current ESRD PPS and based on the Commission's regression analysis

	ESRD PPS values			MedPAC regression values
	Facility-level regression of composite rate services	Patient-level regression of separately billable services	Combined regression results, all ESRD bundle services	Facility-level regression of all ESRD bundle services
LVPA	1.368	0.955	1.239	1.319
Rural location	1.015	0.978	1.008	1.010
Share of treatment cost	80.8%	19.2%	100%	100%

Note: LVPA (low-volume payment adjustment), ESRD (end-stage renal disease), PPS (prospective payment system). CMS derived the ESRD PPS adjustment values by combining the results of (1) a facility-level regression model that used 2012 and 2013 dialysis facility cost reports, with the dependent variable equal to the average cost per treatment for composite rate services, and (2) a patient-level regression model that used 2012 and 2013 dialysis facility claims, with the dependent variable equal to the estimated average payment per patient for dialysis-related drugs and laboratory services. The Commission estimated payment adjustment values based on a single regression that uses 2017 cost report and claims data, with the dependent variable equal to the average cost of ESRD bundle services. The Commission's regression results are significant at $p < .0001$ level for the LVPA and $p < .05$ level for rural location, are based on a regression including 5,151 freestanding facilities, and have an R^2 of 0.3816. Our estimate of the LVPA adjustment is higher than the ESRD PPS factor in part because the ESRD PPS factor is adjusted by the ratio of low volume to other volume category factors, whereas our estimate incorporates other volume category factors into the base rate.

Source: MedPAC analysis of calendar year 2016 final rule, 2017 cost reports submitted by freestanding dialysis facilities to CMS, and dialysis claims.

variable equal to the estimated average payment per patient for dialysis-related drugs and laboratory services.

To calculate the value of each payment adjustment, CMS combined the facility-level regression results with the patient-level regression results by weighting factors from each regression by the share of treatment cost for each set of services (e.g., composite rate share (1.015 × 0.808) + separately billable share (0.978 × 0.192) = 1.008 for the rural payment adjustment).

By contrast, the Commission estimated the payment adjustment values using a single-equation regression, with the dependent variable equal to the average cost of all ESRD bundle services and 2017 cost report and claims data.

The rural location variable in our LVPA and rural regression model (Table 7-6) was found to be statistically significant, meaning that accounting for other factors in the model, rural location is associated with higher treatment costs. Despite the statistical significance of this result, an adjustment for all rural facilities, including those that are high volume or near another facility, would not meet the Commission's other two rural payment principles: Rural payment adjustment should be targeted to low-volume and isolated facilities and should include a way to encourage cost control. We note that the ESRD PPS regression also includes control variables (e.g., additional facility-size categories and organization of ownership) that serve to accurately specify the size of the payment adjustment factors (i.e., the coefficients for payment adjustment variables are more accurately estimated when controlling for other factors that affect average treatment cost). Regression coefficients for control variables may be statistically significant, yet those control variables do not affect payment.[20] For example, facilities associated with large dialysis organizations (LDOs) or other chain organizations were associated with having higher costs than facilities with independent or unknown ownership (statistically significant in our regression results), but LDOs and other chain organizations do not receive a payment increase due to their ownership status.[21] The goal of this policy is to focus payment adjustments on those facilities most essential to ensure access to care, and thus, in our view, a payment adjustment for rural location is not warranted for facilities that are not low volume and

TABLE 7-7 **Estimated LVI payment adjustment values decrease as total treatment volume increases**

	MedPAC regression
	Facility level, all ESRD bundle services
LVI Category 1	1.317
LVI Category 2	1.267
LVI Category 3	1.189
Share of treatment cost	100%

Note: ESRD (end-stage renal disease), LVI (low-volume and isolated). LVI Category 1 comprises facilities with fewer than 4,000 treatments in each of the 3 years preceding the payment year. LVI Category 2 comprises facilities that had fewer than 5,000 treatments in each of the preceding 3 years (excluding LVI Category 1 facilities). LVI Category 3 comprises facilities that had fewer than 6,000 treatments in each of the preceding 3 years (excluding LVI Category 1 and LVI Category 2 facilities). MedPAC regression results are significant at $p < .0001$ level, are based on a regression including 5,151 freestanding facilities, and have an R^2 of 0.3840.

Source: MedPAC analysis of cost reports submitted by freestanding dialysis facilities to CMS and dialysis claims.

not isolated. However, given its statistical significance, rural location could be considered as an addition to the control variables in the ESRD PPS regression model.

Table 7-7 shows regression results for the LVI category adjustments. LVI Category 1 facilities, those with fewer than 4,000 treatments in each of the 3 prior years and farther than 5 miles from the nearest facility, would receive an adjustment of 1.317. LVI Category 2 facilities would receive an adjustment of 1.267, and LVI Category 3 facilities would receive an adjustment of 1.189. The relative size of the three LVI coefficients aligns with evidence showing that facilities providing the fewest treatments have higher average costs, and the statistical significance of each coefficient demonstrates the benefit of expanding the definition of low volume above 4,000 treatments for isolated facilities.

To assess the impact on facility payment rates of replacing the LVPA and rural location adjustments with the LVI category adjustments, we estimated the base rate and payment factors from each regression model and calculated the average facility payment rate based on each model. The impact on facilities depends on their eligibility for any LVI adjustment, the LVPA, and the rural location adjustment. Table 7-8 (p. 202) shows that most facilities meeting our low-volume and isolated criteria would have no change in payment or would receive a payment increase (first three rows of the table), but facilities currently eligible for both the LVPA and rural location adjustment would see a small decrease (fourth row of the table), as the LVI Category 1 factor is smaller than the sum of the estimated the LVPA and rural location adjustment factors. The largest payment increases, 20 percent and 21 percent, would be for facilities that are newly eligible for the low-volume and isolated adjustment based on the expanded definition (i.e., facilities eligible for LVI Category 2 and Category 3 adjustments), depending on whether they are currently eligible for the rural location adjustment.

As shown in Table 7-8 (p. 202), facilities currently eligible for the LVPA, the rural location adjustment, or both but not eligible for the LVI adjustment would see a payment decrease. These facilities are located in a rural area and are not low volume, or they are low volume but located within five miles of another facility. A concern could be that LVPA-eligible facilities that are not isolated (and therefore are not LVI eligible) would receive a 22 percent or 23 percent payment decrease, depending on rural location. However, under the LVPA, Medicare currently subsidizes low-volume facilities that are near other facilities, in contrast to the goal of the LVI adjustment to support only low-volume facilities that are essential to maintain access to dialysis care and thereby improve the value of Medicare's spending. Overall, we find that the payment changes caused by replacing the LVPA and rural

TABLE 7–8

Estimated impact of the Commission's LVI adjustment on average Medicare payment rate for facilities of varying eligibility

Facilities' eligibility to receive:				
LVI adjustment	LVPA	Rural adjustment	Number of facilities	Estimated average Medicare payment change
Yes	No	No	136	21%
Yes	No	Yes	184	20
Yes	Yes	No	83	0
Yes	Yes	Yes	172	–1
No	No	Yes	867	–1
No	Yes	No	173	–22
No	Yes	Yes	49	–23
No	No	No	5,425	0

Note: LVI (low-volume and isolated), LVPA (low-volume payment adjustment). Estimated impact of LVI adjustment is based on the Commission's number of facilities affected using data for all 7,089 freestanding and hospital-based facilities in 2017. Average payment change is based on the Commission's estimates of the LVI adjustment, LVPA, and rural adjustment for 5,823 freestanding facilities.

Source: MedPAC analysis of cost reports and claims submitted by dialysis facilities to CMS.

adjustment with the LVI category adjustments generally align with the Commission's principles that facilities with greater importance for maintaining access to services (those that are isolated) can receive a higher payment rate if such an increase is empirically justified, as demonstrated by our analysis.

Finally, we estimated the impact of switching from the current LVPA and rural adjustment factors to the LVI adjustment across various facility characteristics (e.g., urban/rural, large dialysis organization/other, for profit/nonprofit, freestanding/hospital based). We found that few facilities would experience a significant payment change under the LVI adjustment. Only 8 percent of facilities are affected, falling into one of three mutually exclusive categories: (1) were LVPA eligible but would not be LVI eligible, (2) were LVPA eligible and would be LVI eligible, or (3) were not LVPA eligible but would be LVI eligible. Moreover, a similar number of facilities would experience a significant payment increase or decrease (i.e., 320 facilities would experience a significant payment increase, 265 facilities would experience a significant payment decrease). Given the low share of facilities affected, we did not find a substantial impact for any of the subgroups of facilities we assessed.

Effects of a low-volume and isolated payment adjustment on beneficiaries' access to high-quality care

To assess the potential impact of our illustrative LVI policy on quality, we used each facility's total performance score that CMS calculated under the 2017 ESRD Quality Incentive Program (QIP). Beginning in 2012, outpatient dialysis payments are linked to the quality of care that facilities provide under the ESRD QIP. Under statutory provisions, the maximum payment reduction that CMS can apply to any facility is 2 percent. In 2017, facilities could receive a total performance score ranging from 0 (the lowest) to 100 (the highest) based on the following measures:

- clinical measures that assess vascular access among hemodialysis beneficiaries, dialysis adequacy, bloodstream infections, hospital readmission rates, and presence of hypercalcemia; and
- reporting measures that assess bone mineral metabolism and disease management, anemia management, and the facility's compliance with administering the in-center hemodialysis Consumer Assessment of Healthcare Providers and Systems® survey on a twice-yearly basis.

Among all dialysis facilities (with 2017 QIP data), the QIP total performance score averaged 68.6. The score of facilities that would no longer receive the LVPA under the illustrative LVI policy was not statistically different from the score of the next closest facility (70.9 versus 69.3, respectively, using a paired t-test).

A separate concern involves the potential for predatory competition with low-volume and isolated providers. That is, would an LVI policy allow an organization with sufficient capital reserves to establish a new facility in close proximity to an LVI-eligible facility, thus rescinding the LVI eligibility and reducing Medicare payments to the existing facility in an attempt to put the facility out of business and capture the facility's patient population? In our view, the incentive to engage in such predatory competition could be limited by the generally negative Medicare margins of low-volume facilities (see March 2019 report findings for evidence that low-volume facilities tend to have lower margins) and the requirement to find a new medical director in an area that is likely to be rural (Medicare Payment Advisory Commission 2019b). Our review of new facility openings in 2017 corroborates this view: Just 7 of 302 new facilities opened within 5 miles of an LVPA-receiving facility and only 1 opened within 5 miles of a rural LVPA-receiving facility.

Under the current LVPA policy, an existing facility would not lose its low-volume payment adjustment (23.9 percent increase) if a competing facility opened within five miles of its location because proximity to another facility is considered only for facilities under common ownership. Under the LVI policy, eligible facilities would need to be located farther than five miles from the nearest facility regardless of ownership. To address predatory competition—a new dialysis facility opening within five miles of an existing LVI facility—policymakers could exempt the existing LVI facility from the five-mile distance criterion for a period of three years as long as it continues to meet the volume criteria (i.e., the existing low-volume facility would continue to receive the LVI adjustment for three years, despite being located within five miles of another facility). A three-year exemption from the distance criterion for the existing facility would ensure beneficiaries' access to care and promote competition between the existing and new facility to provide patient-centered high-quality care. At the end of the three-year "exemption" period, a facility would be required to meet both the distance and volume criteria to receive the LVI adjustment.

Policymakers could consider a continuous low-volume and isolated payment adjustment instead of a categorical approach

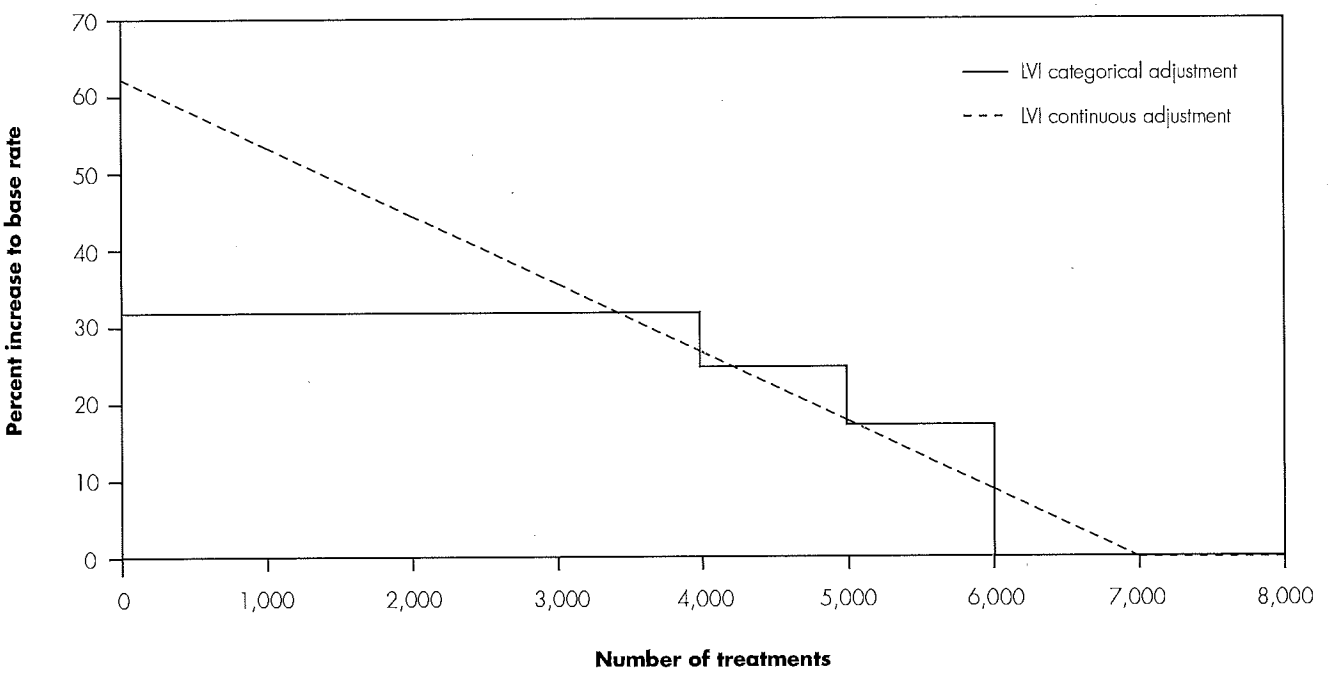
As an alternative to a payment adjustment using categorical variables, a continuous adjustment factor could apply the same eligibility criteria for facility isolation (i.e., no other facilities within 5 miles), but would replace the 3 low-volume categories with a single threshold: fewer than 7,000 treatments, for example, in each of the 3 years (2014, 2015, and 2016) preceding the payment year (2017). (We used a 7,000-treatment threshold to approximately align the facilities eligible for the LVI adjustment with those under the 3-category approach used in our model.)

We conducted a preliminary analysis to illustrate the impact of a continuous adjustment factor. For illustrative purposes, we specified a continuous factor by assigning it a value of 7,000 minus the average annual number of treatments across the preceding years for eligible facilities and a value of 0 for all other facilities. To estimate the marginal cost reduction for providing one additional treatment in eligible facilities if a continuous adjustment were in effect, we used the same regression model that was used to determine the LVI adjustment's effect.

Figure 7-5 (p. 204) shows that a continuous adjustment would have the benefit of smoothing the cliffs, or cut points, associated with categorical adjustments, under which an increase from LVI Category 1 (facilities with fewer than 4,000 treatments) to LVI Category 2 (facilities with between 4,000 and 4,999 treatments) decreases the payment adjustment from about 32 percent to 27 percent. Alternatively, adding more categories to the categorical adjustment could also limit the cliff effect.

A continuous adjustment might be more challenging to administer than a categorical approach. To determine the value of a facility's continuous adjustment, the facility would need to attest to whether the number of treatments provided in each of the three preceding years was lower than the 7,000-treatment threshold. Before the payment year, facilities would also need to provide CMS an estimate of the average annual number of treatments provided across the three years preceding the payment year (i.e., average of actual treatment volume for the first two years of this period and the projected treatment volume for the third year still in progress) and multiply that number by the continuous adjustment factor. This

FIGURE 7-5 **Illustrative example comparing LVI categorical adjustment to LVI continuous adjustment**



Note: LVI (low-volume and isolated).

Source: MedPAC analysis of cost reports submitted by freestanding dialysis facilities to CMS and dialysis claims.

process is slightly more complicated than determining a facility's categorical LVI adjustment (and current LVPA adjustment), which only requires facilities to check whether the number of treatments provided in each of the three preceding years is lower than a threshold. Because of these differences, providers could calculate and predict Medicare rates more easily under a categorical approach.

A continuous adjustment could provide greater accuracy than a categorical adjustment if it is calculated with the empirically determined number of maximum treatments using accurate dialysis cost report data (our analysis used a 7,000-treatment threshold for illustrative purposes only). One concern about using an adjustment with a complex design is that the quality of the underlying cost data may not be sufficient to support that level of accuracy. For example, facilities do not consistently report peritoneal dialysis treatments according to CMS guidelines. One week of peritoneal dialysis should be reported as three hemodialysis-standardized (or equivalent) treatments; however, some facilities report according to the guideline and other facilities report seven daily peritoneal dialysis treatments per week. Some stakeholders advocate for fewer and less complicated adjustments in the ESRD PPS over concern that adjustments reduce the base rate, but those adjustments are paid out to facilities to the same extent they are accounted for in estimating the ESRD PPS. Policymakers should consider how to balance the accuracy of adjustments with the accuracy of the underlying data.

RECOMMENDATION 7-2

The Secretary should replace the current low-volume and rural payment adjustments in the end-stage renal disease prospective payment system with a single adjustment for dialysis facilities that are isolated and consistently have low volume, where low-volume criteria are empirically derived.

RATIONALE 7-2

The design of the current low-volume and rural payment adjustments does not align with the Commission's principles on payments to rural providers: Rural payment adjustments should target facilities that are critical for beneficiary access (meaning those that are both low volume and isolated), the magnitude of payment adjustments should be empirically derived, and the adjustments should encourage provider efficiency.

The current low-volume payment adjustment is applied to facilities that are located near another dialysis facility, does not account for the higher cost of facilities with volumes of 4,000 to 5,999 treatments per year, and uses a single all-or-nothing threshold. The rural adjustment applies to all facilities located in rural areas, regardless of their treatment volume or proximity to another facility. The recommendation would apply to facilities that are necessary to preserve access to care (both low volume and isolated), would better account for facilities with higher cost of treatment, and would mitigate the all-or-nothing application of the current low-volume adjustment. The low-volume and isolated adjustment in the recommendation could be implemented with a categorical or continuous approach. In either case, eligibility for the adjustment and size of the adjustment should be empirically derived.

IMPLICATIONS 7-2

Spending

- The recommendation is intended to be budget neutral with respect to current policy.

Beneficiaries and providers

- The recommendation enhances beneficiaries' access to care at isolated, low-volume facilities. It is not expected to affect providers' willingness or ability to serve beneficiaries. Based on our analysis, payments would increase for providers with lower treatment volumes that are not in close proximity to another facility but currently do not receive the low-volume payment adjustment. Payments would decrease for providers currently receiving the low-volume payment adjustment that are in close proximity to another facility and for providers currently receiving the rural adjustment but have higher volume or are in close proximity to another facility. ■

Endnotes

1 Before 2011, Medicare paid dialysis facilities a prospective payment, referred to as the composite rate, that covered services routinely required for dialysis treatment, including dialysis equipment and supplies, social services, nursing, dietary counseling and other clinical services, and certain laboratory tests and drugs. The composite rate payment bundle did not include certain commonly furnished Part B drugs, including erythropoietin-stimulating agents, iron, and vitamin D agents.

2 A separate method is used to calculate payments for pediatric dialysis beneficiaries (ages 17 and younger), who constitute less than 1 percent of all dialysis beneficiaries.

3 Wage index values vary geographically, tied to the Office of Management and Budget's core-based statistical areas. The wage index values used under the ESRD PPS are the inpatient PPS wage index values calculated without regard to geographic reclassifications and utilize pre-floor hospital data that are unadjusted for occupational mix.

4 Under the drug designation process that CMS established in 2016, new injectable drugs used to treat or manage a condition that are in an existing ESRD-related functional category are considered part of the PPS payment bundle and thus not eligible for a TDAPA.

5 Specifically, for drugs that fall within an existing functional category, the TDAPA ends two years from the effective date of the subregulatory billing guidance that begins the add-on payment.

6 Specifically, CMS is excluding from TDAPA eligibility those drugs approved by the FDA under Section 505(c) of the Food, Drug, and Cosmetic Act and new drugs that the FDA assigns an NDA classification code of Type 3, 5, 7, or 8; Type 3 in combination with Type 2 or Type 4; Type 5 in combination with Type 2; or Type 9 when the "parent NDA" is Type 3, 5, 7, or 8.

7 The rebasing in 2014 resulted in a reduction of the base payment rate by $8.16 per treatment.

8 The specific terms included in the contracts between dialysis organizations and drug manufacturers are not public. However, we can obtain some information from the annual filings that publicly traded companies submit to the Securities and Exchange Commission. For example, in 2017, DaVita entered into a "Sourcing and Supply Agreement" with Amgen for both the oral and intravenous versions of calcimimetics and Epogen, an agreement that concludes in 2022 (DaVita 2019). According to this public document, the contract requires DaVita to purchase Epogen in amounts necessary to meet no less than 90 percent of the company's requirements for erythropoiesis-stimulating agents through the expiration of the contract.

9 This 3-year eligibility period is based on the dialysis facility's as-filed or final settled cost reports for 12 consecutive months. For hospital-based dialysis facilities, when a hospital has multiple locations and treatment counts are aggregated in the hospital's cost report, its MAC may consider other supporting documentation, which may include individual facility treatment counts rather than the hospital's cost report alone.

10 Specifically, a facility attests that it was low volume for the first two eligibility years and that it will be for the third eligibility year. In most cases, the MAC will not have received the third eligibility year's cost report and will rely on the attestation to allow the application of the adjustment.

11 Facilities are eligible for the LVPA if the change in ownership resulted in a change of facility type. According to CMS, common ownership means the same individual, individuals, entity, or entities directly or indirectly own 5 percent or more of each dialysis facility.

12 Across all facilities in 2017, total treatment volume averaged roughly 11,000 treatments.

13 The cost analysis uses 2017 cost reports submitted by freestanding dialysis facilities to CMS. This analysis defines total cost as all services in the PPS payment bundle and adjusts total cost per treatment to remove differences in the cost of labor. Cost report data are unaudited, meaning that they do not reflect the audit that PAMA mandated. In the final rule for the 2019 ESRD PPS, the agency said that the audit process is complete and the audit staff are reviewing the findings (Centers for Medicare & Medicaid Services 2018). Historically, facilities' cost reports have included costs that Medicare does not allow.

14 Urban areas are metropolitan statistical areas (MSAs) or a metropolitan division (which is a smaller group of counties or equivalent entities defined within an MSA containing a single core with a population of at least 2.5 million).

15 We found that more than 100 facilities that were eligible did not receive the LVPA in 2017 (see text box on qualification for the LVPA, p. 191).

16 We exclude hospital-based dialysis facilities because there is no guarantee of consistency in the methods used to allocate hospital costs to dialysis departments and to dialysis cost

categories. CMS has said that expense data for hospital-based cost reports reflect the allocation of overhead of the entire institution and that the expenses of each hospital-based component may be skewed (Centers for Medicare & Medicaid Services 2014).

17 CMS applied a natural log transformation to average treatment costs and used an outer fence methodology to identify average costs that are unusually high or low for exclusion from the regression.

18 The control variables identify facility type as hospital based or freestanding, facility size (4,000 treatments or fewer and ineligible for the low-volume adjustment, 4,000 to 4,999 treatments, 5,000 to 9,999 treatments, and 10,000 or more treatments), ownership type (independent, large dialysis organization, regional chain, unknown), calendar year of data (to combine data from multiple years), and the portion of treatments that included self-dialysis training.

19 Our estimate of the LVPA adjustment is higher than ESRD PPS factor in part because the ESRD PPS factor is adjusted by the ratio of low volume to other volume category factors, whereas our estimate incorporates other volume category factors into the base rate.

20 Instead, the share of costs explained by the intercept and the control variables could be effectively combined into the ESRD base rate (which is the same for all facilities) such that all costs are accounted for in estimating the ESRD PPS base rate and adjustment factors.

21 Similarly, CMS found that facilities associated with large and regional dialysis organizations had higher average dialysis cost per treatment compared with independent freestanding dialysis facilities (Centers for Medicare & Medicaid Services 2009).

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APPENDIX A

Commissioners' voting on recommendations

APPENDIX A

Commissioners' voting on recommendations

In the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000, the Congress required MedPAC to call for individual Commissioner votes on each recommendation and to document the voting record in its report. The information below satisfies that mandate.

Chapter 1: Realizing the promise of value-based payment in Medicare: An agenda for change

No recommendations

Chapter 2: Challenges in maintaining and increasing savings from accountable care organizations

The Secretary should use the same set of national provider identifiers to compute both performance-year and baseline assignment for accountable care organizations in the Medicare Shared Savings Program.

Yes: *Buto, Casalino, Crosson, DeBusk, DeSalvo, M. Ginsburg, P. Ginsburg, Grabowski, Jaffery, Navathe, Perlin, Pyenson, Ryu, Safran, Thompson, Wang*
Absent: *Thomas*

Chapter 3: Replacing the Medicare Advantage quality bonus program

The Congress should replace the current Medicare Advantage (MA) quality bonus program with a new MA value incentive program that:

- scores a small set of population-based measures;
- evaluates quality at the local market level;
- uses a peer-grouping mechanism to account for differences in enrollees' social risk factors;

- establishes a system for distributing rewards with no "cliff" effects; and
- distributes plan-financed rewards and penalties at a local market level.

Yes: *Buto, Casalino, Crosson, DeBusk, DeSalvo, M. Ginsburg, P. Ginsburg, Grabowski, Jaffery, Navathe, Perlin, Pyenson, Ryu, Safran, Thomas, Thompson, Wang*

Chapter 4: Mandated report: Impact of changes in the 21st Century Cures Act to risk adjustment for Medicare Advantage enrollees

No recommendations

Chapter 5: Realigning incentives in Medicare Part D

5-1 The Congress should make the following changes to the Part D prescription drug benefit:

- Below the out-of-pocket threshold:
  - Eliminate the initial coverage limit.
  - Eliminate the coverage-gap discount program.
- Above the out-of-pocket threshold:
  - Eliminate enrollee cost sharing.
  - Transition Medicare's reinsurance subsidy from 80 percent to 20 percent.
  - Require pharmaceutical manufacturers to provide a discount equal to no less than 30 percent of the negotiated price for brand drugs, biologics, biosimilars, and high-cost generic drugs.

Yes: *Buto, Casalino, Crosson, DeBusk, DeSalvo, M. Ginsburg, P. Ginsburg, Grabowski, Jaffery, Navathe, Perlin, Pyenson, Ryu, Safran, Thomas, Thompson*
Abstain: *Wang*

5-2 Concurrent with our recommended changes to the benefit design, the Congress should:

- Establish a higher copayment amount under the low-income subsidy for nonpreferred and nonformulary drugs.
- Give plan sponsors greater flexibility to manage the use of drugs in the protected classes.
- Modify the program's risk corridors to reduce plans' aggregate risk during the transition to the new benefit structure.

Yes: *Buto, Casalino, Crosson, DeBusk, DeSalvo, M. Ginsburg, P. Ginsburg, Grabowski, Jaffery, Navathe, Perlin, Pyenson, Ryu, Safran, Thomas, Thompson*
Abstain: *Wang*

5-3 Concurrent with our recommended changes to the benefit design, the Secretary should:

- Allow plans to establish preferred and nonpreferred tiers for specialty-tier drugs.
- Recalibrate Part D's risk adjusters to reflect the higher benefit liability that plans bear under the new benefit structure.

Yes: *Buto, Casalino, Crosson, DeBusk, DeSalvo, M. Ginsburg, P. Ginsburg, Grabowski, Jaffery, Navathe, Perlin, Pyenson, Ryu, Safran, Thomas, Thompson*
Abstain: *Wang*

Chapter 6: Separately payable drugs in the hospital outpatient prospective payment system

No recommendations

Chapter 7: Improving Medicare's end-stage renal disease prospective payment system

7-1 The Congress should direct the Secretary to eliminate the end-stage renal disease prospective payment system's transitional drug add-on payment adjustment for new drugs in an existing end-stage renal disease functional category.

Yes: *Buto, Casalino, Crosson, DeBusk, DeSalvo, M. Ginsburg, P. Ginsburg, Grabowski, Jaffery, Navathe, Perlin, Pyenson, Ryu, Safran, Thomas, Thompson, Wang*

7-2 The Secretary should replace the current low-volume and rural payment adjustments in the end-stage renal disease prospective payment system with a single adjustment for dialysis facilities that are isolated and consistently have low volume, where low-volume criteria are empirically derived.

Yes: *Buto, Casalino, Crosson, DeBusk, DeSalvo, M. Ginsburg, P. Ginsburg, Grabowski, Jaffery, Navathe, Perlin, Pyenson, Ryu, Safran, Thomas, Thompson, Wang*

Acronyms

Acronyms

3M HIS	3M Health Information Systems
AAGR	average annual growth rate
A-APM	advanced alternative payment model
ACA	Affordable Care Act of 2010
ACO	accountable care organization
ACS	ambulatory care sensitive
AMI	acute myocardial infarction
APC	ambulatory payment classification
APG	ambulatory patient group
AQC	Alternative Quality Contract
ASP	average sales price
AWV	annual wellness visit
B	billion
BBA	Bipartisan Budget Act
BCBS	Blue Cross Blue Shield
BCS	breast cancer screening
CAHPS®	Consumer Assessment of Healthcare Providers and Systems®
CHF	congestive heart failure
CMMI	Center for Medicare & Medicaid Innovation
CMS	Centers for Medicare & Medicaid Services
CMS-HCC	CMS hierarchical condition category
CNS	central nervous system
COPD	chronic obstructive pulmonary disease
C-SNP	chronic condition special needs plan
CV	coefficient of variation
CY	calendar year
DMEPOS	durable medical equipment, prosthetic devices, prosthetics, orthotics, and supplies
DRG	diagnosis related group
D-SNP	dual-eligible special needs plan
EAPG	Enhanced Ambulatory Patient Group
ED	emergency department
EGWP	employer group waiver plan
EHR	electronic health record
ePA	electronic prior authorization
ESA	erythropoiesis-stimulating agent
ESRD	end-stage renal disease
F&B	formulary and benefit
FB	full benefit
FDA	Food and Drug Administration
FFS	fee-for-service
GAO	Government Accountability Office
GDR	generic dispensing rate
HCC	hierarchical condition category
HCPCS	Healthcare Common Procedure Coding System
HEDIS®	Healthcare Effectiveness Data and Information Set®
HMO	health maintenance organization
HOS	Health Outcomes Survey
HVIP	hospital value incentive program
ICL	initial coverage limit
IPPS	inpatient prospective payment system
I-SNP	institutional special needs plan
LDO	large dialysis organization
LICS	low-income cost-sharing subsidy
LIS	low-income [drug] subsidy
LTI	long-term institutionalized
LVI	low volume and isolated
LVPA	low-volume payment adjustment
M	million
MA	Medicare Advantage
MAC	Medicare administrative contractor
MA-PD	Medicare Advantage–Prescription Drug [plan]
MA-VIP	Medicare Advantage value incentive program
MedPAC	Medicare Payment Advisory Commission
MedPAR	Medicare Provider Analysis and Review
MIPPA	Medicare Improvements for Patients and Providers Act of 2008
MMA	Medicare Prescription Drug, Improvement, and Modernization Act of 2003
MMP	Medicare–Medicaid Plan
MSA	metropolitan statistical area
MSSP	Medicare Shared Savings Program
N/A	not applicable
NDA	new drug application
NextGen	Next Generation
NPI	national provider identifier
NTAP	new technology add-on payment
OOP	out of pocket
OPPS	outpatient prospective payment system
PACE	Program of All-Inclusive Care for the Elderly
PAMA	Protecting Access to Medicare Act of 2014
PB	partial benefit

PBM	pharmacy benefit manager
PCP	primary care physician
PDP	prescription drug plan
POS	point of sale
PPO	preferred provider organization
PPS	prospective payment system
PR	predictive ratio
QBP	quality bonus program
QIP	Quality Incentive Program
R&D	research and development
RDS	retiree drug subsidy
RTBT	real-time benefit tool
RxHCC	prescription drug hierarchical condition category
SCI	substantial clinical improvement
SCOD	specified covered outpatient drug
SNP	special needs plan
SPNPT	separately payable non-pass-through
SSA	Social Security Act
TDAPA	transitional drug add-on payment adjustment
TIN	taxpayer identification number
V	version
VBP	value-based payment

More about MedPAC

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Commissioners' biographies

Kathy Buto, M.P.A., is an independent consultant and an expert in U.S. and international health policy. She serves on the Healthcare Leadership Council of the Healthcare Financial Management Association and as a venture adviser to Incube Labs LLC. She also serves on the board of the Arlington Free Clinic and as a member of Women of Impact, a women's health care leadership group. Her previous positions include vice president of global health policy at Johnson & Johnson, senior health adviser at the Congressional Budget Office, deputy director of the Center for Health Plans and Providers at the Health Care Financing Administration (now the Centers for Medicare & Medicaid Services), and deputy executive secretary for health at the Department of Health and Human Services. Ms. Buto received her master's in public administration from Harvard University.

Lawrence Casalino, M.D., Ph.D., is the Livingston Professor of Public Health and chief of the division of Healthcare Policy and Economics in the Weill Cornell Department of Healthcare Policy and Research in New York, NY. His research primarily focuses on physicians, the organization of the health care delivery system, and payment and regulatory policies that impact physicians and the delivery system as well as patients. Among other appointments, Dr. Casalino served as a senior advisor to the director of the Agency for Healthcare Research and Quality. He currently serves on the Congressional Budget Office's Panel of Health Advisors. Dr. Casalino was a primary care physician in private practice for 20 years. He received his M.D. from the University of California, San Francisco, and his Ph.D. in health services research from the University of California, Berkeley.

Francis J. Crosson, M.D., spent 35 years as a physician and physician executive at Kaiser Permanente. In 1997, he founded and then for 10 years led the Permanente Federation LLC, the national umbrella organization for the physician half of Kaiser Permanente. Later he served as senior fellow at the Kaiser Permanente Institute for Health Policy and director of public policy for The Permanente Medical Group. From July 2012 through October 2014, he was group vice president of the American Medical Association in Chicago, IL, where he oversaw work related to physician practice satisfaction, efficiency, and sustainability. He previously served on MedPAC from 2004 to 2010, including as vice chair from 2009 to 2010. Dr. Crosson received his medical degree from the Georgetown University School of Medicine.

Brian DeBusk, Ph.D., is chief executive officer of DeRoyal Industries in Powell, TN, which operates in the surgical, orthopedic, wound care, and health care information technology markets. He also serves as vice chairman of the Board of Trustees of Lincoln Memorial University in rural Tennessee, which includes graduate medical education programs for physicians, physician assistants, nurse practitioners, and nurses. Dr. DeBusk's prior employment includes General Electric, Inobis, and Pace Energy Systems. He has served on the faculty of both the University of Tennessee and Lincoln Memorial University, teaching classes in information technology and business strategy. Dr. DeBusk holds a Ph.D. in electrical engineering from Vanderbilt University and a master of business administration from Emory University.

Karen DeSalvo, M.D., M.P.H., M.Sc., is chief health officer at Google Health. She also is an adjunct professor of medicine and population health at the Dell Medical School at the University of Texas at Austin and co-convener of the National Alliance to Impact the Social Determinants of Health. She is also president of the Society of General Internal Medicine and serves on the board of directors for Welltower. Before joining the University of Texas, Dr. DeSalvo was dually appointed as the acting assistant secretary for health and the national coordinator for health information technology at the Department of Health and Human Services. She has also served as the New Orleans health commissioner and as vice dean for community affairs and health policy at Tulane School of Medicine. Dr. DeSalvo received her medical and public health degrees from Tulane University School of Medicine, where she also completed her residency and fellowship in internal medicine. She has a master's degree in clinical epidemiology from the Harvard School of Public Health.

Marjorie Ginsburg, B.S.N., M.P.H., is the founding executive director of the Center for Healthcare Decisions Inc., which she ran from 1994 to mid-2016. In that role, she was responsible for the design, implementation, and evaluation of projects and programs that fostered civic engagement around health policy issues that affected

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Paul B. Ginsburg, Ph.D., is the Leonard Schaeffer Chair in Health Policy Studies at the Brookings Institution in Washington, DC, and professor of health policy at the University of Southern California, where he is affiliated with the USC Schaeffer Center for Health Policy and Economics. He directs the USC-Brookings Schaeffer Initiative for Health Policy. Prior positions include founder and president of the Center for Studying Health System Change, founding executive director of the Physician Payment Review Commission, senior economist at RAND, and deputy assistant director at the Congressional Budget Office. Dr. Ginsburg earned his doctorate in economics from Harvard University.

David Grabowski, Ph.D., is a professor in the Department of Health Care Policy at Harvard Medical School in Boston, MA. His research primarily focuses on the economics of aging, with an emphasis on post-acute and long-term care financing, organization, and delivery of services. Dr. Grabowski served as a member of several CMS technical expert panels related to home health and skilled nursing facility payment and quality. He serves on the editorial board of several journals, including the *American Journal of Health Economics*. Dr. Grabowski received his Ph.D. in public policy from the Irving B. Harris School of Public Policy at the University of Chicago.

Jonathan Jaffery, M.D., M.S., M.M.M., is a professor of medicine at the University of Wisconsin School of Medicine and Public Health. Dr. Jaffery serves as senior vice president/chief population health officer at UW Health and as president of UW Health ACO Inc., where he is responsible for the overall development, coordination, and implementation of the population health strategy. A board-certified nephrologist, Dr. Jaffery holds a B.A. in Russian literature from the University of Michigan and an M.D. from The Ohio State University College of Medicine. He completed an internal medicine residency and nephrology fellowship at the University of Vermont. A former Robert Wood Johnson Foundation Health Policy Fellow and chief medical officer for the Wisconsin State Medicaid program, Dr. Jaffery has graduate degrees from the University of Wisconsin School of Medicine and Public Health and the University of Southern California Marshall School of Business.

Amol Navathe, M.D., Ph.D., is codirector of the Healthcare Transformation Institute and associate director of the Center for Health Incentives and Behavioral Economics in the Department of Medical Ethics and Health Policy at the University of Pennsylvania's School of Medicine. He is also an assistant professor at Penn and staff physician at the Corporal Michael J. Crescenz VA Medical Center in Philadelphia, PA. Dr. Navathe's research group designs, tests, and evaluates payment models for national insurers and state Blue Cross Blue Shield plans. He leads the American Hospital Association's national bundled payment collaborative to disseminate evidence-based best practices. Among other appointments, Dr. Navathe was formerly a managing director, Healthcare Value Transformation, at Navigant. Dr. Navathe received his M.D. from the University of Pennsylvania and his Ph.D. in health care management and economics from the Wharton School at the University of Pennsylvania.

Jonathan Perlin, M.D., Ph.D., M.S.H.A., is the president of clinical services and chief medical officer of HCA Healthcare in Nashville, TN. In that role, he has leadership responsibility for clinical services and improving performance at HCA's hospitals and other sites of service. Before joining HCA, Dr. Perlin was Under Secretary for Health in the U.S. Department of Veterans Affairs. Dr. Perlin is a member of the National Academy of Medicine and has faculty appointments at Vanderbilt University and Virginia Commonwealth University. Dr. Perlin received his Ph.D. in pharmacology and his medical degree from the Medical College of Virginia at Virginia Commonwealth University, where he also completed his residency training in internal medicine.

Bruce Pyenson, F.S.A., M.A.A.A., is principal and consulting actuary at Milliman Inc. in New York, NY. His work has focused on diverse aspects of health care and insurance, including recent work related to alternative payment models for accountable care organizations, such as shared savings, as well as financial modeling of therapeutic interventions. He has co-authored publications on such topics as the cost-effectiveness of lung cancer screening, pandemic influenza, and site-of-service cost differences for chemotherapy. Mr. Pyenson is a fellow of

the Society of Actuaries and a member of the American Academy of Actuaries. He is adjunct clinical associate professor of New York University's College of Global Public Health.

Jaewon Ryu, M.D., J.D., is the president and CEO for Geisinger, an integrated health care system headquartered in Danville, PA, that comprises hospitals, employed providers, a health plan, a medical school, and research and innovation centers. He previously served as president of integrated care delivery at Humana and held leadership roles at the University of Illinois Hospital & Health Sciences System and at Kaiser Permanente. Dr. Ryu received his undergraduate education at Yale University and his medical and law degrees from the University of Chicago, after which he completed his residency training in emergency medicine at Harbor-UCLA Medical Center.

Dana Gelb Safran, Sc.D., is head of measurement for Haven, the health care venture formed by Amazon, Berkshire Hathaway, and JPMorgan Chase. In that role, she is part of the organization's core leadership team and is responsible for applying data, analytics, and measurement to optimize the venture's success. Dr. Safran was previously chief performance measurement and improvement officer at Blue Cross Blue Shield of Massachusetts (BCBSMA). As an architect of the BCBSMA Alternative Quality Contract and the leader responsible for its unique use of behavioral economics and payer-provider collaboration to reduce cost while improving quality, Dr. Safran is widely recognized as having contributed to the national push toward value-based payment. Before joining BCBSMA, she led a research institute at Tufts University School of Medicine dedicated to developing patient-reported measures of health and health care quality. She remains on the faculty at Tufts and serves on a number of state and national advisory bodies related to health care quality and affordability. She earned her master's and doctor of science degrees from the Harvard School of Public Health.

Warner Thomas, M.B.A., is president and CEO of the Ochsner Health System in New Orleans, LA. He oversees a network of 40 owned, managed, and affiliated hospitals and specialty hospitals, more than 100 health and urgent care centers, and more than 4,500 employed and affiliated physicians. Ochsner is the only Louisiana hospital recognized by U.S. News & World Report as a "Best Hospital" across three specialty categories caring for patients from all 50 states and more than 60 countries worldwide each year. The Ochsner Health System operates one of the largest accredited non-university-based graduate medical education programs in the United States. It is also one of the largest Medicare risk contractors in the region and offers an accountable care organization for Medicare. Mr. Thomas's prior positions include chief operating officer of Ochsner Health System, vice president of managed care and network development at the Southern New Hampshire Medical Center, and senior auditor and consultant at Ernst & Young. He received his master of business administration from Boston University Graduate School of Management.

Susan Thompson, M.S., B.S.N., is interim president and chief executive officer of UnityPoint Health, an integrated delivery system serving Iowa, central and western Illinois, and central Wisconsin. She is also the chief executive officer of UnityPoint Health Accountable Care LC, an Iowa limited liability company that brings together a diverse group of health care providers including hospitals, employed and independent physicians, and other providers, as well as other health initiatives. Previously, she was senior vice president of integration and optimization for UnityPoint and was president and chief executive officer of UnityPoint Health–Fort Dodge, which serves a predominantly rural and aging population and includes a sole community hospital, a primary care and multispecialty physician group, management contracts with five critical access hospitals throughout the region, and a Pioneer Accountable Care Organization. She also served in successive clinical and management positions at Trinity Regional Medical Center, as intensive care staff nurse, director of quality systems, assistant director of patient-focused care, chief information officer, chief operating officer, and chief executive officer. Ms. Thompson obtained her B.S. in nursing and her M.S. in health services management from Clarkson College in Omaha, NE.

Pat Wang, J.D., is president and chief executive officer of Healthfirst in New York, NY. Healthfirst is a not-for-profit provider-sponsored health plan that serves Medicare enrollees, including those who are eligible for low-income subsidies and those who are dually eligible for Medicare and Medicaid. Healthfirst incorporates a value-based payment model that aligns incentives with hospital and physician partners. Ms. Wang previously served as senior vice president of finance and managed care for the Greater New York Hospital Association. She received her law degree cum laude from the New York University School of Law.

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